No. 05-35264

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RANCHERS CATTLEMEN ACTION LEGAL FUND
UNITED STOCKGROWERS OF AMERICA,
Plaintiff-Appellee,

v.

UNITED STATES DEPARTMENT OF AGRICULTURE,
Animal and Plant Health Inspection Service; et al.,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of Montana

BRIEF FOR APPELLANTS

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BRIEF FOR APPELLANTS

STATEMENT OF JURISDICTION

Plaintiff invoked the jurisdiction of the district court pursuant to 28 U.S.C. § 1331. On March 3, 2005, the district court entered a preliminary injunction barring the implementation of a United States Department of Agriculture (USDA) regulation. Excerpts of Record (ER) 108-137. A timely notice of appeal was filed on March 17, 2005. ER 413-415; Fed. R. App. P. 4(a)(1)(B). The order granting the preliminary injunction is appealable under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUES

1. Whether the district court erred in setting aside the determination of the Secretary of Agriculture, made on the basis of notice-and-comment rulemaking, that it is not necessary to ban Canadian cattle less than 30 months old and certain beef products to avoid dissemination in this country of Bovine spongiform

encephalopathy (BSE), commonly known as "mad cow disease."

2. Whether the court erred in holding that the rulemaking violated the Regulatory Flexibility Act.

3. Whether the court erred in holding that the rulemaking violated the National Environmental Policy Act.

4. Whether the court erred in concluding that an injunction was required to avoid dissemination of BSE on the basis of its decision to set aside the Secretary's contrary determination.

STATEMENT OF THE CASE

Bovine spongiform encephalopathy is a neurological disease in cattle, transmitted through animal feed containing protein from other infected animals. The disease was described and diagnosed for the first time in the United Kingdom in 1986. Based on the knowledge available at the time, the Secretary of Agriculture restricted imports from all countries in which BSE occurred, expanding the restrictions over time to include additional countries which were determined to present an undue risk of introducing BSE into the United States.

In January 2005, the Secretary for the first time adopted a comprehensive scheme for evaluating the risks posed by ruminants and ruminant products from nations in which BSE has occurred as well as cattle from nations in which it has not occurred to date. The new regulations drew on the scientific knowledge developed since BSE was first diagnosed as well as the standards and guidelines developed by international bodies with the

participation of the United States. The rule, promulgated after notice and comment, explained that the occurrence of BSE in another country would not, of itself, present an absolute bar to imports of ruminants and ruminant products. Instead, the risk would be assessed in light of the effectiveness of that nation's regulatory scheme as well as domestic safeguards ensuring against the introduction of the disease. Imports would be permitted only if the foreign nation had adopted crucial risk mitigation procedures. In particular, because BSE is transmitted by the recycling of infected animal tissue, a ban on ruminant protein in ruminant feed would be essential. In addition, the Secretary would consider whether the nation conducted effective surveillance to ensure compliance and detect possible outbreaks, and whether it had responded swiftly and effectively to diagnosed cases of BSE.

Applying these criteria, the Secretary concluded that restrictions on Canadian cattle under 30 months old, imported for purposes of slaughter, were not necessary to preclude dissemination of BSE in United States livestock. The Secretary noted Canada has had an effective feed ban in place since 1997, conducts surveillance far exceeding international standards, and responds rapidly and effectively to identified instances of BSE.

To further ensure against the possible dissemination of BSE, the Secretary permitted only importation of cattle under 30 months of age. Because BSE has an extended incubation period,

animals of this age would not have developed significant levels of infectivity in their tissues, even if exposed. Moreover, cases of BSE in very young cattle have been linked to extremely high doses of infectious material, and none has occurred in Canada. Because Canadian cattle under 30 months old would be born and reared long after the feed ban was in place, it is highly unlikely they would have been exposed to BSE at all, much less exposed at levels that would result in a case of BSE at 30 months of age. As the Secretary stressed, the isolated instances of BSE in Canadian cattle had been traced to cattle born before or near the time the feed ban was instituted, and none of the cows - each of which was six or seven years old - would have been subject to import under the new rule.

The Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF) filed suit to enjoin the rule before its effective date in March 2005. The district court granted a preliminary injunction barring implementation of the rule. The court held that R-CALF was likely to succeed on its claims that the rule violated the Administrative Procedure Act, the National Environmental Policy Act, and the Regulatory Flexibility Act and that the balance of harms favored injunctive relief.

This is an appeal from the preliminary injunction.

STATEMENT OF FACTS

I. BACKGROUND.

A. The Animal Health Protection Act.

The Animal Health Protection Act, 7 U.S.C. § 8301 et seq., provides that the Secretary of Agriculture "may prohibit or restrict . . . the importation or entry of any animal . . . if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock." 7 U.S.C. § 8303(a)(1). The Animal and Plant Health Inspection Service (APHIS) is the agency within the Department of Agriculture that regulates the importation of animals and animal products to guard against the introduction of various animal diseases to the United States.

B. Bovine Spongiform Encephalopathy.

Bovine spongiform encephalopathy, commonly known as "mad cow disease," is a progressive and fatal neurological disorder of cattle. See generally ER 109 (District Court Opinion (Op.) at 2); 70 Fed. Reg. 460, 461-62 (Jan. 4, 2005). BSE was first diagnosed in the United Kingdom (U.K.) in 1986, and over 95% of all BSE cases have occurred in the U.K., where the epidemic peaked in 1992 and 1993. Id. at 461-62.

Since the disease was first diagnosed, scientists have concluded that it is a member of the family of diseases known as

transmissible spongiform encephalopathies (TSE) and believe that the infectious agents in this family are prions, which are an abnormal form of normal cellular proteins. Id. at 461. With respect to BSE, this abnormality is spread from one cow to another not through normal forms of contact, but by one animal's ingestion of the infected protein of another animal. Ibid.; see also id. at 486 ("In cattle, oral ingestion of feed contaminated with the BSE is the only documented route of field transmission of the disease."). This disease spread as a result of the practice, once prevalent in the U.K., of including rendered ruminant products in cattle feed.

Human exposure to BSE through consumption of contaminated cattle products can cause variant Creutzfeldt-Jakob Disease (vCJD), a chronic and fatal neurodegenerative disease. Id. at 462. In total, about 153 probable and confirmed cases of vCJD have been identified worldwide, most of which are linked to exposure in the U.K. Ibid. Since more than 1 million cattle may have been infected with BSE during the epidemic in the U.K., the relatively small number of British cases of vCJD suggests there is a substantial species barrier that may protect humans from widespread illness due to BSE. Research indicates "that the level or amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle," ER 63 (Engeljohn Dec. ¶ 15); see also 70 Fed. Reg. at 462, 505. There have been no probable or confirmed cases of vCJD from

Canadian beef.

C. USDA's Response to the United Kingdom Epidemic.

In response to the BSE epidemic in the U.K., the Secretary began restricting the importation of live ruminants and most ruminant products from regions affected with BSE or presenting a BSE risk. See, e.g., 56 Fed. Reg. 19794 (Apr. 30, 1991) (interim rule); 56 Fed. Reg. 63865 (Dec. 6, 1991) (final rule); see also 70 Fed. Reg. at 462. When new cases appeared in additional countries, those nations were simply added to the regulations.

When a cow infected with BSE was diagnosed in Alberta, Canada in May 2003, an interim rule was issued adding Canada to the list of countries affected with BSE, thereby halting imports of Canadian cattle and most Canadian beef. See 68 Fed. Reg. 31,939, 31,940 (May 29, 2003).

II. THE PRESENT RULEMAKING.

In November 2003, the Secretary issued a proposed rule that for the first time set out a comprehensive approach to determining what regions pose a "minimal risk" of introducing BSE to the United States through the importation of ruminants and ruminant products. 68 Fed. Reg. 62,386 (Nov. 4, 2003). The proposed rule explained why the infected cow discovered in May 2003 did not require a total ban on live cattle imports. Id. at 62,389-62,390. During the pendency of the rulemaking, in December 2003, a case of BSE was diagnosed in Washington State in

a cow of Canadian origin. The Secretary addressed that case in a subsequent Federal Register notice. See 69 Fed. Reg. 10,633 (Mar. 8, 2004); ER 111 (Op. at 4). Although the Secretary did not believe that discovery of the new case altered the relevant analysis, he nonetheless reopened and extended the comment period on the proposed rule until April 7, 2004. 69 Fed. Reg. at 10,633. In total, the agency received 3,379 public comments. See 70 Fed. Reg. at 465.

A. The Need To Revisit Prior Practice.

The final rule issued on January 4, 2005, 70 Fed. Reg. 460, incorporated the advances in scientific knowledge and the work of the international community in responding to BSE. Id. at 463 ("A significant amount of research has been conducted on BSE since the disease was initially identified.").

The Secretary noted the proven effectiveness of control measures adopted in response to early epidemiological work that identified contaminated feed as the only documented method of spreading the disease between cattle. In particular, feed bans preventing the recycling of the agent have been overwhelmingly successful even in Europe where exposure is assumed to be the highest. Ibid. The Secretary also explained that studies had identified specific tissues such as those from the brain and spinal cord as particularly likely to harbor the infectious agent. By removing these tissues, the greatest potential source of infection can be removed from the food chain. 70 Fed. Reg. at

463. The Secretary declared that "[t]his increased body of knowledge provides a sound and compelling scientific basis for more focused regulatory restrictions with regard to BSE than those we have been operating under." Ibid.

The Secretary also cited the evolution of BSE guidelines adopted by the Office International des Epizooties (OIE), also referred to as the World Organisation for Animal Health. As the Secretary noted, the OIE is recognized by the World Trade Organization (WTO) as the international organization responsible for development and periodic review of standards, guidelines, and recommendations with respect to animal health and diseases. The United States, which is a member of the OIE, has been actively involved in the development of OIE guidelines. The OIE guidelines reject the assumption that the occurrence of BSE, of itself, requires suspension of cattle or beef imports from that nation, and instead provides a system of risk classification. Ibid.

The Secretary also cited complementary regulatory activity undertaken by the Food and Drug Administration and the Department of Agriculture's Food Safety and Inspection Service (FSIS), which create additional barriers to introduction of BSE into the food chain even if a case of the disease occurs. As the Secretary noted, the risk posed by importation of cattle or beef cannot be considered without reference to the overall regulatory framework now in place. 70 Fed. Reg. at 465-66.

B. **Relevant Criteria For Evaluating Risk.**

The regulation sets out the criteria that will guide the Secretary in determining whether a nation poses a "minimal risk" so that a complete ban of live cattle and beef imports is not required.

First, the nation must have in place risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. These measures include import restrictions sufficient to minimize the possibility of introduction of the agent and a ban on the feeding of ruminant protein to ruminants that is effectively enforced. In addition, the nation must conduct surveillance for BSE at levels meeting or exceeding OIE recommendations.

Second, if BSE has been detected, the nation must have conducted an epidemiological investigation sufficient to confirm that the measures it has in place are sufficient to prevent the further introduction or spread of BSE.

Third, if BSE has been detected, the nation must have taken additional risk mitigation measures, as necessary, and must continue to take such measures. 70 Fed. Reg. at 463.

C. **Risk Posed By Canadian Cattle Under 30 Months.**

Applying these criteria, the Secretary concluded that no basis existed for continuing to restrict all live cattle imports from Canada.

The Secretary explained that Canada had instituted appropriate risk mitigation measures, including a feed ban instituted in August 1997. Canada has met or exceeded the OIE-recommended level of BSE surveillance for the past 7 years. See id. at 468.

The Secretary then addressed Canada's response to reported incidents of BSE in a cow in Alberta in May 2003, and in a cow of Canadian origin in Washington State in December 2003. Canada and the United States conducted a rigorous epidemiological investigation of both occurrences and concluded the animals were born before the implementation of the feed ban in 1997, with exposure most likely occurring before or near that time. Id. at 468-69; 68 Fed. Reg. at 62,389-62,390 (explaining May 2003 cow "was born before the implementation of the feed ban").

Finally, the Secretary noted that Canada has taken additional risk mitigation measures based on a risk analysis. In July 2003, responding to the recommendations of an international review team of animal disease experts, Canada began requiring animal tissue posing special risks (known as SRMs, see infra at 23, 39-40) be removed at slaughter, several months before the United States established similar requirements. Canada had also repeatedly increased its level of BSE surveillance and testing. 70 Fed. Reg. at 468.

As noted, the Secretary permitted importation only of cattle under 30 months. The cattle must be accompanied by a certificate

from a Canadian government veterinarian establishing that the animals are less than 30 months old and have been subject to a ruminant feed ban. Id. at 480, 548. They may only be imported through designated entry ports, and, if they are being sent to a feedlot, they must be permanently marked to identify them as having been imported from Canada. Id. at 479 (branding country of origin), 482 (government seals affixed to conveyance at port of entry). Animals sent to a feedlot must be slaughtered before they reach 30 months of age. Id. at 485. The final rule was scheduled to go into effect on March 7, 2005. Id. at 460.

In January 2005, two more BSE-infected cows were discovered in Alberta. The timing of these incidents prevented the Secretary from addressing them in the preamble to the final rule, but Canada's investigation confirmed that one cow was born in 1996 and most likely was exposed to feed produced prior to Canada's August 1997 feed ban. The investigation also disclosed that the second cow was born in 1998 and is likely to have consumed feed produced prior to the August 1997 feed ban or shortly thereafter. See 70 Fed. Reg. 18,252, 18,255, 18,258 (Apr. 8, 2005) (Addendum 7, 10). In response, the Secretary delayed the applicability of the portion of the rule that would have permitted the importation of certain Canadian beef products derived from cattle 30 months of age or older. 70 Fed. Reg. 12,112 (Mar. 11, 2005) (Addendum 1); ER 122-123 (Op. at 15-16). It bears noting, however, that USDA's analysis and conclusions

with regard to risk had already acknowledged and accounted for the possibility that additional animals with BSE born at or near the time the feed ban was implemented would be identified. The mitigation measures were designed with this possibility in mind. See 70 Fed. Reg. at 514.

III. DISTRICT COURT PROCEEDINGS.

Plaintiff Ranchers Cattlemen Action Legal Fund United Stockgrowers of America (R-CALF) brought this action seeking declaratory and injunctive relief against the USDA prohibiting it from implementing the new rule. After filing its complaint, R-CALF sought a preliminary injunction against the implementation of the rule.

The district court granted the injunction. It held that R-CALF was likely to succeed in demonstrating that the final rule violated the APA because it was arbitrary and capricious in several different respects. ER 115-124 (Op. at 8-17). The district court also held that R-CALF was likely to succeed on its claim under the National Environmental Policy Act, ER 125-128 (Op. at 18-21), and the Regulatory Flexibility Act, ER 129-131 (Op. at 22-24). Finally, in the district court's view, the balance of the harms and the public interest tipped in R-CALF's favor. ER 131-133 (Op. at 24-26). Accordingly, it preliminarily enjoined the final rule.

SUMMARY OF ARGUMENT

I. The Secretary of Agriculture concluded that an absolute ban on live ruminants and ruminant products is not required to prevent dissemination of BSE in the United States. The district court enjoined all imports as specified in the rule because it believed that assessment was incorrect.

The Secretary of Agriculture is no less committed to avoiding dissemination of BSE than the district court. The only question is whether the district court erred as matter of law in its evaluation of the regulation and impermissibly substituted its evaluation of risk for that of the Secretary.

As shown below, the record leaves no doubt that the court did precisely that, ignoring detailed explanations and scientific data and turning instead to unfounded speculation and patently erroneous calculations. Because an injunction cannot properly be premised on an error of law, reversal would be required for that reason alone. Here, however, the legal error cannot be divorced from the court's assessment of irreparable harm. Because the court had no basis for setting aside the Secretary's determination that a total ban is not required, it likewise had no reason to conclude that maintenance of such a ban is required to preclude dissemination of BSE.

Although the court speculated that its injunction might avoid economic harm to plaintiffs, it is beyond dispute that the continued restrictions on imports results in enormous hardship to

the domestic meat processing industry. The injunction enhances the economic position of the plaintiffs, who are its only real beneficiary, while inflicting harm on others. At the same time, the injunction strains relations between the United States and Canada, which have cooperated closely to achieve the shared goal of avoiding dissemination of BSE.

In raising the specter of a health threat to humans, the court ignored the relevant science. There have been no probable or confirmed cases of vCJD from Canadian beef. Indeed, all evidence indicates there is a substantial species barrier to human transmission and the amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle. Moreover, because the Secretary's rule would permit only the importation of cattle products from which SRMs are removed and live cattle under 30 months old under specified conditions, the dreadful possibilities contemplated by the district court's decision have no nexus to the reality confronting the Secretary.

II. The governing statute vests broad authority in the Secretary to restrict imports when he believes such restrictions are necessary, and there is no suggestion that the Secretary failed to adhere to any applicable statutory standard. Nor can there be any serious question that the agency explained every aspect of its decision in detail, drawing on the vast body of scientific knowledge developed since the disease was first

diagnosed in the late 1980s, the international guidelines developed with the active participation of the United States, and the thousands of comments submitted during the rulemaking.

Consistent with international standards, the Secretary concluded that the occurrence of BSE in another country does not, of itself, require that all imports of ruminants and ruminant products be banned. The salient question, the Secretary explained, was whether that country had in place a regulatory scheme comparable to that in the United States, which minimizes the possible development of BSE in the first instance and ensures that it will not be disseminated if it in fact occurs. Because BSE is transmitted by recycling infected tissue in cattle feed, the establishment of a feed ban like that in place in the United States and Canada is of crucial importance. The country must also conduct adequate testing and demonstrate its ability to respond to and isolate any instance of the disease.

Even with these measures in place, the rule limits imports to cattle under 30 months old for purposes of slaughtering before they attain that age. This age limitation is of critical importance because BSE has a long incubation period and animals of this age would not have developed significant levels of infectivity even if exposed. 70 Fed. Reg. at 483; 68 Fed. Reg. at 62,390; ER 320. Moreover, such animals would be born long after Canada implemented a feed ban and adopted a regulatory regime that is comparable to that in the United States. Thus,

little risk exists that the cows would have been exposed to BSE at all, much less at the levels that would produce a case of BSE in cattle under 30 months old. As the Secretary explained, the isolated instances of BSE in Canada have occurred in the rapidly decreasing population of cattle born before or near the time that the feed ban was instituted. When instances have been identified, Canada has immediately taken appropriate steps and nothing suggests that these instances reflect a broader dissemination of the disease or failures in the regime that has been in place since 1997. Because the infected cattle were all well over 30 months of age, none would have been eligible for importation under the rule.

Far from according deference to the Secretary's scientific judgment, the district court ignored the detailed explanations contained in the regulation and the studies on which they were based, reaching mistaken conclusions based on inaccurate calculations and a series of erroneous premises.

III. The court's invalidation of the regulation under the Regulatory Flexibility Act (RFA) underscores its willingness to ignore settled limitations on judicial review of executive action. The RFA requires that an agency consider comments. It does not alter the terms of the statutory authority at issue or impose new substantive requirements. The court invalidated the regulation because the Secretary purportedly failed to consider requiring a country-of-origin label and a regime of optional

slaughterhouse testing for BSE. The rule in fact addressed both these issues. Contrary to the district court's view, nothing in governing law required the agency to adopt these suggestions.

IV. The district court similarly erred in enjoining operation of the rule on the basis of asserted failures to comply with procedural requirements of the National Environmental Policy Act (NEPA). Plaintiff R-CALF is an association of stock growers created to protect the economic interests of its members, and the injury claimed here is economic. As this Court has made clear, however, purely economic injury does not fall within the zone of interests protected by NEPA and is insufficient to establish prudential standing. Similarly, because R-CALF's mission is at best marginally related to environmental concerns, it cannot establish the requisite organizational standing to pursue its NEPA challenge.

In any event, plaintiff's NEPA claims are without merit. Contrary to the district court's ruling, the agency provided greater opportunity for comment than would be required. Having received comments on its proposed rule and environmental assessment, the agency was not required to solicit another round of comments. That it issued its final rule and final environmental assessment before that additional round was completed did not deprive any commenter of the ability to present concerns to the agency. Moreover, in issuing its finding that the rule will have no significant environmental impact, the

agency addressed all comments, most of which duplicated comments received earlier. R-CALF's assertion that the agency failed to examine some impacts from the rule is particularly wide of the mark because it provided no comments pertaining to those alleged impacts during the comment periods on the environmental assessments. Indeed, the district court wrongly reproved the agency for failing to address issues that no commenter presented.

STANDARD OF REVIEW

This Court reviews the grant of a preliminary injunction for abuse of discretion. Southwest Voter Registration Educ. Project v. Shelley, 344 F.3d 914, 918 (9th Cir. 2003) (en banc). "The district court's interpretation of the underlying legal principles, however, is subject to de novo review and a district court abuses its discretion when it makes an error of law." Ibid.

ARGUMENT

"To obtain a preliminary injunction, a party must demonstrate either: (1) a likelihood of success on the merits and the possibility of irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in its favor." Clear Channel Outdoor v. City of Los Angeles, 340 F.3d 810, 813 (9th Cir. 2003) (internal quotation marks omitted).

It is common ground that avoiding a credible threat of

dissemination of BSE is of paramount importance. The district court could find such a threat only by setting aside the Secretary's determination that a ban on importation of cattle products and live cattle under 30 months old is not necessary to avoid dissemination of the disease. Because that ruling is wholly without basis, the court's assessment of the merits and its assessment of the harms are equally flawed.

I. NO BASIS EXISTS FOR SETTING ASIDE THE BSE RULE

A. The Regulation Is Entitled To the Utmost Deference.

The governing statute provides that the Secretary of Agriculture "may prohibit or restrict" the importation of ruminants or ruminant products "if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction . . . of any pest or disease of livestock." 7 U.S.C. § 8303(a)(1). The statute provides no standards by which to measure the Secretary's exercise of discretion, and establishes no circumstances in which the Secretary is required to impose an importation ban. As this Court has recognized, the use of the word "may" connotes that the decision is entrusted to the agency's discretion. See, e.g., United States v. George, 85 F.3d 1433, 1437 (9th Cir. 1996) (citing Tashima v. Administrative Office of the United States Courts, 967 F.2d 1264, 1273 (9th Cir. 1992)), for the proposition that a statute's use of the word "may" demonstrates a "congressional intent to give [the]

decisionmaker discretion"); Adams v. FAA, 1 F.3d 955, 956 (9th Cir. 1993). Indeed, the decision to close the borders closely resembles the type of enforcement decision that is not susceptible to judicial review. Heckler v. Chaney, 470 U.S. 821, 830 (1985).

The broad grant of authority reflects the nature of the determination that the Secretary is entrusted to make. See generally H. Conf. Rep. No. 107-424, reprinted in 2002 U.S.C.C.A.N. 141 (noting Congress had not included definition of disease to give the Secretary maximum flexibility and avoid diversion of resources in litigation). As this Court has emphasized, when "a court reviews an agency action 'involv[ing] primarily issues of fact,' and where 'analysis of the relevant documents requires a high level of technical expertise,' we must 'defer to the informed discretion of the responsible federal agencies.'" Vigil v. Leavitt, 381 F.3d 826, 833 (9th Cir. 2004) (citations omitted); see also United States v. Alpine Land & Reservoir, 887 F.2d 207, 213 (9th Cir. 1989) ("Deference to an agency's technical expertise and experience is particularly warranted with respect to questions involving . . . scientific matters."). A court should be particularly reluctant to second-guess an agency's judgment when, as here, an agency is "making predictions, within its area of special expertise, at the frontiers of science." Baltimore Gas & Elec. v. Natural Res. Def. Council, 462 U.S. 87, 103 (1983). As this Court has

recognized, "[w]hen specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive." Greenpeace Action v. Franklin, 14 F.3d 1324, 1332 (9th Cir. 1992).

B. Based On An Extensive Record, The Secretary Concluded That When Effective Safety Measures Are In Place, Occurrences of BSE Do Not Of Themselves Require An Absolute Ban Of All Cattle and Beef Imports From The Region.

1. The Secretary engaged in a comprehensive analysis of the risks posed by regions in which cases of BSE have been identified, examining the agency's past practice and fully setting out the basis for the new regulation.

The agency's practice of barring all imports of ruminants and most ruminant products from countries in which BSE has occurred arose in response to the BSE epidemic in the United Kingdom in the late 1980s and early 1990s. 70 Fed. Reg. at 461-62. At that point, the very existence of the disease had only been recently established and the efficacy of controls to prevent its dissemination had yet to be established.

Since that time, the scientific understanding of the disease and its management have been transformed, and a variety of controls have been established in the United States and in other nations, including Canada, that guard against dissemination of the disease if it should occur.

The overwhelming efficacy of risk mitigation procedures has now been firmly established. As the Secretary noted, after early epidemiological work identified the crucial role of contaminated feed in spreading the disease, feed bans that prevent the recycling of the infective agent have been overwhelmingly successful even in Europe where exposure is assumed to be the highest. Id. at 463.

Measures adopted by the Food and Drug Administration and USDA's Food Safety and Inspection Service also ensure that an occurrence of BSE would not result in dissemination of the disease. Id. at 465-66. Since 1997, the FDA has regulated feed mills, renderers, protein blenders, other feed production sources and ruminant feeders to prevent the recycling of potentially infectious tissue through ruminant feed. See 21 C.F.R. § 589.2000. The FDA's inspections have revealed a high level of compliance with the feed ban. 70 Fed. Reg. at 466.

In January 2004, USDA's Food Safety and Inspection Service adopted three rules to prevent the BSE agent from entering the human food supply. See 69 Fed. Reg. 1861 (Jan. 12, 2004); see also 70 Fed. Reg. at 466. First, FSIS designated certain cattle tissues as special risk materials, or "SRMs," and prohibited their use in human food. In cattle 30 months and older, SRMs include the brain, skull, eyes, spinal cord, and certain other nervous system tissues. SRMs also include the tonsils and distal ileum of all cattle. The FSIS rule requires slaughterhouses to

ensure that SRMs are completely removed from the carcass and segregated from edible product. The FDA subsequently adopted similar rules to prohibit the use of certain cattle products, including SRMs, in FDA-regulated products, including dietary supplement and cosmetics.

Second, FSIS prohibited products produced by Advanced Meat Recovery systems from being labeled as "meat." FSIS found that the technology employed by these systems, which allows processors to remove skeletal muscle tissue from bones, sometimes included spinal cord and nervous system tissue.

Third, FSIS prohibited the use of certain stunning devices that posed a risk of driving fragments of brain tissue into an animal's circulatory system, where they might become lodged in edible tissues. 70 Fed. Reg. at 466.

The most authoritative independent study to date, conducted even prior to the latest protections introduced by FSIS, concluded that the domestic controls in effect as of 2001 minimized the risk of the spread of BSE even if it were introduced into the country in the first instance. ER 173-182. The study, conducted by the Harvard Center for Risk Analysis and the Center for Computational Epidemiology at Tuskegee University, "quantified potential human exposure" to BSE by "analyz[ing] the risk that BSE would spread if introduced into the United States." 70 Fed. Reg. at 505-06. The Harvard-Tuskegee Study "evaluated the potential for the establishment and spread of BSE in this

country if 10 infected cows were introduced into the United States" and concluded that "based on the preventive measures already in place," it would be "extremely unlikely" for BSE "to become established in the United States," id. at 506. Indeed, even assuming the "worst case values," the Study predicted that "the results were not substantially different" and still predicted an "extremely small potential for human exposure." Ibid. Furthermore, as the Secretary noted, "[w]ith the additional safeguards implemented in the United States in 2004 . . . this already small potential is reduced even further." Ibid.

In considering appropriate criteria, the Secretary also looked to the experience of the OIE in developing international guidelines, an effort in which the United States has been actively involved. The OIE guidelines reject the premise that occurrence of BSE, of itself, requires suspension of all cattle and beef imports, and instead provides a system of risk classification. 70 Fed. Reg. at 463.

2. The criteria adopted by the final regulation, like criteria adopted by the OIE guidelines, focus on a region's employment of efficacious risk mitigation measures and response to detected cases of BSE. Risk mitigation measures must include an effective ban on the feeding of ruminant protein to ruminants, coupled with surveillance for BSE at levels that meet or exceed OIE recommendations. If BSE has been detected, the region must

conduct an epidemiological investigation sufficient to confirm that the measures it has in place are sufficient to prevent the further introduction or spread of BSE and must, on an ongoing basis, take additional risk mitigation measures as appropriate. Ibid.

The scope of permissible live cattle imports is subject to a further limitation: cattle must be under 30 months old and can be imported only for purposes of slaughter before they reach the age of 30 months. This restriction is crucial because BSE has an incubation period of several years. Of cattle that developed BSE during the epidemic in the U.K., only 0.01 percent were less than 30 months old. See ER 320; ER 77 (Ferguson Dec. ¶ 11).

Moreover, all evidence indicates that the expected incubation period for Canadian cattle would be significantly longer. The period of incubation varies directly with the amount of infected material consumed. In the rare cases in which BSE has occurred in cattle less than 30 months old, the disease has been linked to the consumption of a relatively large dose of the BSE agent at an early age. ER 320-321. The level of infectious agent in the feed supply in the U.K. prior to the BSE epidemic dwarfs the level of such material present in feed subject to a feed ban such as those in Canada and the United States. ER 77, 82-83 (Ferguson Dec. ¶ 11, 15-16). Indeed, no case of BSE in an animal aged 30 months or less has occurred in the U.K. since 1996. ER 319. With respect to Canadian cattle, the 30-month

rule also ensures that all cattle imported will have been born long after Canada imposed its feed ban in 1997. The cattle are thus extremely unlikely to have been exposed to BSE at all, much less at the levels that would result in a case of BSE before the age of 30 months. ER 321.

C. The Secretary's Determination That A Total Ban On Canadian Cattle and Beef Imports Is Not Necessary To Prevent Dissemination of the Disease in the United States Is Fully Supported by the Record.

Applying these criteria, the Secretary concluded that imports of beef and live cattle under 30 months old from Canada would not result in the introduction of BSE into the U.S. and that a ban on all imports was not justified. As the agency explained, Canada began restricting imports of live cattle from the U.K. and Ireland in 1990. In 1993, Canada traced and killed all of the cattle that it had been imported from the U.K. and Ireland. In 1996, Canada prohibited the import of live ruminants from any country that was not free of BSE. 70 Fed. Reg. at 467.

In 1997, Canada banned the feeding of mammalian protein to ruminants. Ibid. Canadian authorities inspect all feed manufacturing and rendering facilities on a regular basis, and the inspections verify high levels of compliance with the feed ban. Id. at 468. In addition, Canada has far exceeded the OIE-recommended level of BSE surveillance. Whereas OIE guidelines specify testing of about 300 cattle each year, Canada last year

tested 23,500, see ibid.,[1] and expects to test at least 30,000 cattle in 2005, a level of surveillance that far exceeds international standards and is in proportion to the number of cattle tested in the United States, id. at 469; ER 314-315. Indeed, Canada has taken some risk mitigation measures even in advance of the United States, requiring that "special risk materials" or SRMs, such as the tonsils and distal ileum be removed from cattle at slaughter even before such restrictions became effective in the United States. As the USDA explained, with these measures in place, "the likelihood of the spread and establishment of BSE in Canada" is "negligible." 70 Fed. Reg. at 468.

Canada's response to the detection of cases of BSE fully comports with the regulation's expectations. Following reported cases of BSE in May 2003 and December 2003, Canada and the United States conducted epidemiological investigations and concluded that the animals were born before the implementation of the feed ban in 1997, with exposure most likely occurring before or near that time. The investigations identified the feed that likely gave rise to the infection, and herds that might have been exposed to that feed were destroyed. Post-mortem tests showed no further evidence of infection. See 68 Fed. Reg. at 62,389-62,390

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[1] Canada's most recent figures for 2004 are found at http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/surv/surve.shtml (last visited Apr. 12, 2005).

(May 2003 cow); 69 Fed. Reg. at 10,634 (December 2003 cow).

Although the publication of the final rule pre-dated the discovery of two more BSE-infected cows in Alberta in January 2005, those discoveries in no way undermine the rationale of the regulation. Canada's investigation confirmed that one cow was born in 1996 and most likely was exposed to feed produced prior to Canada's August 1997 ban. The investigation also disclosed that the second cow was born in 1998 and is likely to have consumed feed produced prior to the August 1997 ban or shortly thereafter. 70 Fed. Reg. at 18,255, 18,258 (Addendum 7, 10). Like the other two cases of BSE in 2003, neither of these cows would have been eligible for importation under the rule. It bears noting, however, that USDA's analysis and conclusions with regard to risk had already acknowledged and accounted for the possibility that additional animals with BSE that were born at or near the time the feed ban was implemented would be identified. The mitigation measures were designed with this possibility in mind. See 70 Fed. Reg. at 514.

D. In Impermissibly Substituting Its Judgment For That Of The Secretary, The District Court Ignored The Explanations And Data In The Rule and the Administrative Record.

As shown below, each of the bases cited by the district court for setting aside the regulation is independently flawed. More fundamentally, however, the court misconceived its role. The governing statutory language, which the court did not cite,

provides that the Secretary may prohibit or restrict imports when he determines it to be necessary. When the Secretary proceeds through comprehensive rulemaking and sets out the basis for his actions in cogent detail, a court has no license to second-guess the Secretary's determination.

The court appeared to believe that its inquiry was materially changed because the Secretary previously banned all cattle imports from Canada. The district court cited the Supreme Court's statement in Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 41-42 (1983), that because a "settled course of behavior embodies the agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress," there is "a presumption that those policies will be carried out best if the settled rule is adhered to." However, the court paid no heed to the context in which the statement was made or the Supreme Court's holding. In State Farm, the agency, implementing a congressional directive to promulgate automobile safety standards, had issued regulations requiring installation of air bags. It then rescinded its requirements without altering its view of the efficacy of airbags. As then-Justice Rehnquist's concurrence observed, "the agency should explain why it declined to leave those requirements intact," but "[i]n this case, the agency gave no explanation at all." Id. at 58. The Court made absolutely clear that the governing standard of review was not altered. It did not require

the Secretary to overcome a presumption that the previous rule had been correct. It simply held that the agency was required to provide a reasoned explanation for its actions.

In sharp contrast, the Secretary here explained his reasoning in full, and the district court did not conclude otherwise: it simply disagreed with the reasoning. Moreover, unlike State Farm, the decision here is based on advances in scientific knowledge. The Secretary's original regulations were issued when it was impossible to evaluate risk based on the proven efficacy of mitigation procedures. The present rulemaking was the first occasion in which the agency addressed such procedures and incorporated them into its regulations. Here, the Secretary was in no way relaxing import requirements, but merely substituting equally effective measures based on sound science to achieve the same level of protection.

Finally, the decision here is different in kind than that in State Farm. There, Congress had required promulgation of a safety standard and the issue, broadly speaking, was whether that standard should include air bags. Here, the Secretary must make what are, in effect, a series of discretionary determinations regarding the risks posed by various ruminant and ruminant product imports, and there is no reason to believe that an approach first adopted when the world reacted with panic and considerable ignorance to the U.K. epidemic should be thought to have any particular or continuing validity.

As shown below, the district court adopted each of seven erroneous theories advanced by plaintiffs, none of which withstands scrutiny.

1. **"Quantitative" Determination of Risk**.

The district court began by quarreling with the very notion that the Secretary could analyze the import question in terms of minimal risk. In the district court's view, the Secretary was required to provide a quantitative definition of "minimal." ER 116-117 (Op. at 9-10). The Secretary, the court opined, offered only inherently "subjective conclusions" that cannot be verified by "support in the administrative record," leaving courts unable to "asses[s] the merits" of the agency's actions. ER 116 (Op. at 9).

This reasoning is difficult to fathom. The Secretary's reasoning is laid out in detail and supported by a variety of scientific studies discussed in the rule. The overarching point of the regulation is that interlocking safety measures will prevent the risk of introduction and dissemination of BSE. It is unclear why or how that conclusion should or could be restated in quantitative form, although some of the many studies in the record, like the Harvard-Tuskegee study, provide quantitative risk analysis. See 70 Fed. Reg. at 504-05.

Indeed, the record abounds in highly relevant numbers. The regulation, for example, permits imports only of cattle under 30 months. Canadian cattle of that age would have been born and

reared under a rigorous regulation regime substantially identical to that in the United States, and none of the cases of BSE in Canada have involved cattle even close to that age. In other words, the Secretary found no reason to believe that cattle subject to importation will have BSE or that they pose any particular risks at all.

Moreover, the court's reasoning stands the statutory language on its head. The Secretary "may prohibit or restrict" the importation of an animal "if the Secretary determines that the prohibition or restriction is necessary[.]" 7 U.S.C. § 8303(a)(1). That language does not remotely suggest that the Secretary is required to state his ultimate conclusion in mathematical form. As this Court has noted, "'[e]ven when an agency explains its decision with 'less than ideal clarity,' we "will not upset the decision on that account 'if the agency's path may reasonably be discerned.'" Vigil, 381 F.3d at 833 (quoting Alaska Dep't of Envtl. Conservation v. EPA, 540 U.S. 461, 497 (2004)). This Court has never suggested that requisite clarity is absent when an agency examines relevant studies and lays out its reasoning in detail.

Disregarding relevant authority, the district court relied on Harlan Land Co. v. USDA, 186 F. Supp. 2d 1076, 1094 (E.D. Cal. 2001), in which the district court held that the risk analysis relied on by the Department of Agriculture was flawed because the authors had failed to explain "what information and data was

used" at each step of the analysis. Id. at 1094. Even on its own terms, the decision provides no support for the district court's ruling.

2. **Rate of BSE Incidence in Canada**.

Although the Secretary concluded that Canada's testing for BSE had been exemplary, the district court concluded that "Canada has not conducted sufficient testing for BSE." ER 117 (Op. at 10). The district court based this conclusion on the fact that Canada has tested only 40,000 cattle, while the United States has tested 200,000.

As the court was obliged to acknowledge, however, this disparity in absolute numbers reflects the fact that the Canadian cattle population is many times smaller than the American cattle population. As the Secretary observed, Canada has met or exceeded OIE guidelines for surveillance in every year since 1995. 70 Fed. Reg. at 512.

Believing that Canadian testing had been inadequate, the district court then conducted its own calculation of the incidence of BSE in Canada. See ER 117-118 (Op. at 10-11). It noted that four Canadian cattle from Alberta out of approximately 40,000 tested had been diagnosed with BSE in the past year and a half and then extrapolated that result over the entire Canadian cattle population for only one year, finding an incidence of BSE of 5.5 per million.

This exercise was misconceived in every respect. Its

calculation of the incidence of BSE rested on at least two mistaken premises. First, the court had no basis for extrapolating testing results in Alberta (the area in which BSE has occurred) over the entire cattle population, thereby creating an artificially inflated incidence. The approach has no more merit than an attempt to identify the incidence for Canada as a whole based on testing from a province where no incident of BSE has ever been reported. See ER 72 (Ferguson Dec. ¶ 8). The court further increased the incidence of BSE by accruing cases from more than one year. Internationally accepted practice under OIE guidelines measures incidence on the basis of incidents arising in a single year. That is the case in the European countries invoked by the court as a basis of comparison. If Canada's BSE incidence is measured by year in accordance with accepted practice, the incidence rate in 2003 was 0.33 cases per million, and in the last 12 months it was 0.36 cases per million, as compared to the 5.5 cases per million found by the district court. ER 72-73 (Ferguson Dec. ¶ 8). Canada's incidence rate is well below the relevant OIE guidelines for minimal risk regions. 70 Fed. Reg. at 464.

Apart from these erroneous calculations, the court ignored the fact that none of the cattle infected with BSE would have been eligible for import under the Secretary's rule because they were older than 30 months. It likewise gave no heed to the fact that the incidence of BSE provides substantial confirmation that

the prevalence in Canada is exceedingly low because all the cows were born before or shortly after the time the feed ban was instituted, thereby removing the only known source of BSE transmission in cattle. 68 Fed. Reg. at 62,389 - 62,390; 70 Fed. Reg. at 468-69; 70 Fed. Reg. at 18255, 18258 (Addendum 7, 10).

3. Sufficiency of Canadian Feed Ban

With equal lack of justification, the court concluded that the Secretary had no basis for believing Canada's feed ban to be adequate.

First, the court questioned the significance of a feed ban at all, opining that "there is no conclusive scientific proof" that cattle feed is the "only route" of BSE exposure because "recent scientific data suggests" that BSE may be "transmitted by blood and perhaps saliva." ER 119 (Op. 12). The court found that the Secretary had acted arbitrarily because it "did not acknowledge" these possibilities. Ibid.

If the district court meant to suggest that the Secretary did not address this issue, it was quite wrong, as the court recognized later in its opinion. See ER 121 (Op. at 14) ("The USDA has acknowledged the possible transmission of BSE through blood."). However, the Secretary, unlike the district court, did not believe that scientific evidence on this point is ambiguous. The Secretary observed that some "recent scientific studies have indicated that blood may carry some infectivity for BSE," but that "those studies have concerned blood transfusions." 70 Fed.

Reg. at 491. Moreover, those blood transfusions involved only sheep and mice, and USDA concluded that these studies cannot be extrapolated to the transmission of BSE in cattle - a view that is the "consensus among scientists involved in this work," particularly those within the European Commission Scientific Steering Committee. ER 63 (Engeljohn Dec. ¶ 16). As the Secretary explained, "[i]n cattle oral ingestion of feed contaminated with the BSE is the only documented route of field transmission of the disease." 70 Fed. Reg. at 486 (emphasis added).

The district court then questioned the efficacy of the Canadian feed ban on various grounds. The court noted that the feed ban "allow[s] rendered animal fat in cattle feed," ER 121 (Op. at 14), and observed that tallow infected with BSE may create a risk of the transmission of BSE. Ibid. (citing 70 Fed. Reg. at 501).

As the Secretary explained, however, because the agent of BSE is an abnormal form of a normal protein, animal fat poses a risk only if it contains protein. See 70 Fed. Reg. at 461 (agent of BSE is abnormal form of protein); id. at 501 ("risks associated with tallow will result from protein impurities that may be present in the end product"). Thus, USDA permits importation of tallow from a minimal risk region such as Canada only if it is protein free, that is, has a maximum level of insoluble impurities of 0.15% by weight. Id. at 500-01. As the

Secretary noted, the Canada's feed ban "prohibits materials that are comprised of protein" while exempting non-protein animal products. Id. at 491.

The district court further concluded that Canada's feed ban had not been in place for a sufficient period, noting that OIE's risk-assessment guidelines recommend that a feed ban should have been in place for at least eight years. ER 119 (Op. at 12). Canada's feed ban was instituted in August 1997, somewhat less than eight years before the Secretary's rule was scheduled to take effect in March 2005. The agency concluded that this small difference did not alter the relevant analysis in light of "all of the actions Canada has taken to prevent the introduction and control the spread of BSE (e.g., import controls, level and quality of surveillance, effectiveness of feed ban, epidemiological investigation of detected cases, and depopulation of herds possibly exposed to suspected feed sources)." 70 Fed. Reg. at 470. Finally, the OIE does not recommend that the United States reject Canada for minimal-risk region status merely because its feed ban has not been in place for 8 years. Instead, the OIE would expect the United States to conduct a risk analysis to determine whether an alternative risk mitigation measure, such a restricting the age of live cattle imported, could be applied to achieve the same level of protection. See ER 106A (Wilson Dec. ¶ 7). This is precisely what the USDA did.

The court speculated that the reported incidence of BSE

might demonstrate that the feed ban lacked efficacy. The court conjectured that the four infected Canadian cows could have become infected after the feed ban was put in place in 1997 by subtracting 4.2 years from the age of the animal at death. The mean figure of 4.2 years for the onset of BSE infectivity was based on data collected in the U.K. epidemic, which represented the most intense exposure to BSE that has ever occurred. As discussed, when cattle are subject to lower doses than those documented in the U.K., the incubation period is more extended. ER 319-321. This is entirely consistent with the views of the U.S. and Canadian scientists who investigated the cases and concluded that the exposure occurred before or shortly after the feed ban was implemented in 1997.

4. Removal of SRMs

The district court found that "current scientific evidence" calls into question whether the removal of SRMs from the cattle's carcass means that there is "no risk of exposure to BSE." ER 122 (Op. at 15). It found the USDA's "failure to explain clearly why these concerns do not undercut its reliance on SRM removal requirements" to be arbitrary and capricious. Ibid.

The opinion attacks a straw man. The agency has never claimed that it is "reasonable to presume that there is no risk of exposure to BSE infectious agents" once SRMs are removed. Ibid. The removal of SRMs is one of a multitude of overlapping and inter-dependent mitigation measures on which USDA's rule

relies. See, e.g., 70 Fed. Reg. at 542 ("Removal of SRMs at slaughter and other required risk-mitigating measures of the rule will ensure that beef entering from Canada satisfies animal health criteria the same as or equivalent to those required in the United States.") (emphasis added).

The agency was entirely correct in believing that removal of SRMs is an important part of USDA's overall mitigation scheme. SRMs are "[t]issues that have demonstrated infectivity," and they "must be removed and disposed of as inedible" precisely because they pose an increased risk of BSE. Id. at 502. Ignoring the actual significance of the SRM regulation, the district court improperly disregarded its role in a comprehensive regulatory framework.

5. Breeding of Imported Cattle

The district court concluded that the rule improperly fails to "prohibit cattle of breeding age from being bred either before or after entering the U.S.," "does not require any calves born by imported Canadian cattle to be euthanized," and "does not require the spaying of heifers or castration of bulls, nor does it require heifers to be pregnancy checked as a condition of entry into the U.S." ER 123 (Op. at 16). In this way, the court believed, the agency had opened "a vector for BSE infection in the U.S." Ibid.

The court's ruling pays no heed to the fact that the regulation permits live cattle to enter the United States

only for immediate slaughter or for feeding and then immediate slaughter. See 70 Fed. Reg. at 485 ("[W]e are making no changes in this final rule to allow the importation of cattle from BSE minimal-risk regions other than those for immediate slaughter, or for feeding [and then] slaughter, at less than 30 months of age."). And to ensure that imported cattle who would be fed before slaughter were not diverted for breeding, the agency's rule requires the "conveyance carrying feeder cattle from the U.S. port of entry to a feedlot [to be] sealed in the region of origin with seals of the national government of the region of origin." Id. at 482. The conveyances would remain sealed until the cattle arrive at the feedlot, where they are unsealed by an accredited veterinarian or government official. Ibid. Thus, breeding of Canadian cattle in the United States is a practical impossibility; imported cattle will be either immediately slaughtered or fed and then immediately slaughtered. See id. at 484 ("In effect, this provided for the continued prohibition on the importation of breeding cattle."); id. at 485 ("at this time we are not providing for the importation of such [breeding] animals from BSE minimal-risk regions"); id. at 515 ("Breeding cattle of any age may not be imported into the United States from Canada under this rule.").

Moreover, the scientific basis of the district court's fears is highly questionable. As the agency noted, "[a]lthough some evidence suggesting maternal transmission exists, such

transmission has not been proven and, if it occurs at all, it occurs at very low levels not sufficient to sustain an epidemic." Id. at 515.

6. Fetal Bovine Serum

The court held that USDA acted in an arbitrary and capricious manner "[b]y failing to issue regulations" to prohibit the importation of fetal bovine serum when the agency had stated in its preamble that it was necessary to do so. ER 123-123 (Op. at 16-17). That ruling disregards the fact that existing regulations already prohibit the importation of fetal bovine serum. See 9 C.F.R. § 95.4(d) (prohibiting the importation of "serum albumin, serocolostrum, amniotic liquids or extracts, and placental liquids derived from ruminants that have been in any region listed in § 94.18(a)").

7. Mandatory BSE Testing

The district court also found the rule arbitrary and capricious because, in its view, the USDA failed "to give careful consideration to the benefits and costs of mandatory testing." ER 124 (Op. at 17). Once again, the administrative record is flatly to the contrary. The Secretary explained that "no live animal tests exist for BSE." 70 Fed. Reg. at 475; see also id. at 485. With current testing methods, testing clinically normal cattle at slaughter provides little useful information for surveillance purposes because current testing methods can detect

a positive case of BSE only 2 to 3 months before the animal begins to demonstrate clinical signs. Id. at 475. Thus, even if infection were present, testing clinically normal adult animals at slaughter would not be likely to disclose the presence of the infectious agent. In fact, such testing likely results in 92% false negatives. See ER 75 (Ferguson Dec. ¶ 10); 70 Fed. Reg. at 475, 534. This fact also explains why such testing is not a food safety test and is not deemed appropriate for the purposes suggested by R-CALF. See infra at 45.

II. THE RULEMAKING FULLY SATISFIED THE REQUIREMENTS OF THE REGULATORY FLEXIBILITY ACT.

The court's invocation of the Regulatory Flexibility Act to invalidate the regulation only highlights the extent to which it disregarded the Secretary's careful response to all relevant issues and comments.

The RFA requires agencies to consider the effect that their regulations will have on small entities, including small businesses. See generally Washington v. Daley, 173 F.3d 1158, 1171 (9th Cir. 1999). When applicable, it requires an agency to make available for public comment an initial regulatory flexibility analysis describing a proposed rule's effect on small businesses, 5 U.S.C. § 603(a), while discussing significant alternatives that could accomplish the same objectives while reducing any significant economic impact on small businesses, id. § 603(c). The final regulatory flexibility analysis must

describe steps taken to minimize that impact and must explain why it rejected "other significant alternatives" proposed by commenters. Id. § 604(a)(5). As this Court has explained, "the analyses required by the RFA are essentially procedural hurdles; after considering the relevant impacts and alternatives, an administrative agency remains free to regulate as it sees fit." Environmental Defense Center v. EPA, 344 F.3d 832, 879 (9th Cir. 2003).

The district court found that the agency had violated the RFA in two respects. First, it held that USDA "did not consider" that the rule's effect on small businesses could have been mitigated by requiring Canadian cattle or beef products to be labeled with their country of origin, "so that consumers could choose not to purchase those products." ER 129-130 (Op. at 22-23). However, contrary to the district court's declaration, the agency did explicitly consider a labeling requirement. See 70 Fed. Reg. at 533. It noted that, effective in 2006, the Farm Security and Rural Investment Act of 2002, Pub. L. No. 107-171 § 10816, 116 Stat. 134, 535, will require USDA "to implement a mandatory country of origin labeling program (COOL)." 70 Fed. Reg. at 533. See 7 U.S.C. § 1638a ("a retailer of a covered commodity shall inform consumers . . . of the county of origin of the covered commodity"); id. § 1638(2)(A)(i) (beef is a covered commodity). Inasmuch as Congress has separately imposed a labeling requirement and has determined its appropriate effective

date, the agency did not believe it appropriate to adopt another requirement in connection with this regulation. The agency further explained that a labeling alternative was "not a food safety or animal health measure" at all, 70 Fed. Reg. at 533, but a consumer information and marketing device that does not, in and of itself, do anything to ensure that food is safe or animals are free of disease.

The district court also mistakenly concluded that USDA "did not assess" the alternative of "allowing slaughter facilities to voluntarily test cattle for BSE," an alternative that "would mitigate the adverse effects on small businesses of diminished consumer confidence." ER 130 (Op. at 23). To the contrary, USDA noted that it "has considered carefully the possibility of allowing private companies to conduct their own BSE testing." 70 Fed. Reg. at 534. It rejected that alternative, however, because private testing would be inconsistent with the agency's "mandate to ensure effective, scientifically sound testing for significant animal diseases and to maintain domestic and international confidence in U.S. cattle and beef products." Ibid. As explained above, supra at 43, the agency noted that such testing is ineffective and will produce little useful information.

III. THE ADOPTION OF THE BSE RULE DID NOT VIOLATE NEPA.

The National Environmental Policy Act requires federal agencies to examine the environmental effects of proposed federal actions, and to inform the public of the environmental concerns

that were considered in the agency's decisionmaking. "NEPA itself does not mandate particular results, but simply prescribes the necessary process." Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989). See also Natural Resources Defense Council v. EPA, 859 F.2d 156, 169 (D.C. Cir. 1988) ("NEPA does not * * * expand the range of final decisions an agency is authorized to make," and "does not expand an agency's substantive powers.").

Under NEPA, an agency must prepare a detailed, comprehensive "environmental impact statement" only if a proposal is a "major Federal action[] significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C). Regulations promulgated by the Council on Environmental Quality ("CEQ") provide that an agency may prepare an environmental assessment ("EA") to determine whether a proposed action is likely to have a significant impact on the environment and whether an EIS is necessary. 40 C.F.R. §§ 1501.3, 1501.4. The EA is to be a concise document containing sufficient evidence and analysis for the agency to determine whether to prepare an EIS or a finding of no significant impact ("FONSI"), if it determines through the preparation of an EA that the proposed action will not have a significant effect on the quality of the human environment. 40 C.F.R. §§ 1501.4(b), 1508.9(a)(1), 1508.13.

A. R-CALF Lacks Standing To Pursue Its NEPA Claims.

A plaintiff with standing to challenge an underlying rule may not have prudential standing to challenge NEPA compliance. Purely economic injury falls outside the "zone of interests" that NEPA is intended to protect. Nevada Land Action Ass'n v. United States Forest Serv., 8 F.3d 713, 716 (9th Cir. 1993). As the Court explained, "[t]he purpose of NEPA is to protect the environment, not the economic interests of those adversely affected by agency decisions." Ibid.

Plaintiff's NEPA claims are premised on allegations of economic injury to its members. See ER 3 (Compl. at 3, ¶ 2); see also ER 47-49 (Bullard Dec. ¶¶ 4-9); ER 40-43 (Vansickle Dec. ¶¶ 6-14). That asserted harm reflects R-CALF's mission, which is to protect the economic interests of its members. R-CALF "is a nonprofit cattle association representing over 12,000 U.S. cattle producers on issues concerning international trade and marketing." ER 3 (Compl. at 3 ¶ 2). As its website explains, "R-CALF USA's mission is to represent the U.S. cattle industry in national and international trade and marketing issues to ensure the continued profitability and viability of U.S. independent cattle producers." The Official R-CALF USA Website, http://www.r-calfusa.com/ (Last visited April 12, 2005). The purely economic harms alleged by plaintiff fail to bring it within the zone of interests protected by the statute.

For related reasons, R-CALF also cannot demonstrate

organizational standing. R-CALF not only fails to allege environmental harms particular to R-CALF's members, Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992), but it cannot meet its burden of showing that the interests it seeks to protect are "germane to the organization's purpose." Hunt v. Washington State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977). As an organization formed to protect economic interests, any alleged environmental concerns are at best "marginally related" to R-CALF's organizational purpose. Clarke v. Securities Indus. Ass'n, 479 U.S. 388, 399 (1987). See generally Town of Stratford v. FAA, 285 F.3d 84, 89 (D.C. Cir. 2002).

Plaintiff's unsubstantiated allegation that its members will be harmed because they are beef eaters and will face an "increased risk of disease," ER 3 (Compl. at 3, ¶ 2), only underscores its failure to demonstrate the most basic elements of organizational standing. R-CALF is not an association of beefeaters: it is an association of stockgrowers. That some of its members may eat beef is wholly irrelevant to the organization's composition and purpose, which has nothing to do with protecting the environment for beefeaters.

B. Plaintiff's NEPA Claims Are Without Merit.

The Secretary's finding that the regulation will have no significant environmental impact, like the regulation itself, is subject to deferential review. See Greenpeace Action v. Franklin, 14 F.3d 1324, 1331-32 (9th Cir. 1992). As in other

aspects of its decision, the court found a series of purported failures, none of which has any basis.

1. USDA Allowed Sufficient Public Comment On Its Environmental Assessment

Contrary to the district court's understanding, the agency provided ample opportunity for public comment on its environmental assessment. Although no regulation specifically requires that USDA have a formal notice and comment period for the publication of an environmental assessment, several CEQ regulations address public involvement in the NEPA process, and this Court has held these regulations "to mean that the public must be given an opportunity to comment on draft EAs and EISs." Citizens for Better Forestry v. USDA, 341 F.3d 961, 970 (9th Cir. 2003)(citation omitted). This Court has "not established a minimum level of public comment and participation required by the regulations governing the EA and FONSI process." Ibid.

The agency issued its original draft EA (ER 158) for public comment simultaneously with the proposed rule which was published on November 4, 2003, and provided a public comment period of sixty days for this EA. 68 Fed. Reg. at 62,386, 62,400. The Final EA, issued on January 4, 2005 (ER 278), announced the commencement of another thirty-day comment period, 70 Fed. Reg. 554 (Jan. 4, 2005). That comment period was extended an additional 14 days following the discovery of several citation errors in the first version of the Final EA. 70 Fed. Reg. 3183

(Jan. 21, 2005). In total, therefore, the agency allowed more than 100 days of public comment on the environmental issues raised by the Rule, including 45 days of comment following the publication of the Final EA.

The court nevertheless held that the agency "neglected to provide the public the opportunity to comment on the [Final EA] because the [Final EA] was published after the Final Rule was signed." ER 127 (Op. at 20 (citing California v. Block, 690 F.2d 753, 770 (9th Cir. 1982))).

The agency's call for comments following the Final EA exceeded its obligations under NEPA, which required only the initial comment period following the October 2003 draft EA. The agency is permitted to revise its environmental compliance documents by elaborating on issues presented by the initial draft without triggering a new round of comments each time. "[T]o avoid perpetual cycles of new notice and comment periods, a final rule that is a logical outgrowth of the proposal does not require an additional round of notice and comment even if the final rule relies on data submitted during the comment period." Building Indus. Ass'n v. Norton, 247 F.3d 1241, 1246 (D.C. Cir. 2001). Because the Final EA was nearly double the length of the first draft, the agency in its discretion concluded that a second round of comments would be helpful. It did not, by so doing, render its EA invalid on procedural grounds.

The district court erred in ignoring this framework and

looking instead to Block, in which this Court relied on a CEQ regulation pertaining specifically to draft environmental impact statements, which does not create an obligation to recirculate an EA for public comment after an initial comment period on the draft EA. Block, 690 F.2d at 769-70 (citing 40 C.F.R. § 1500.7(a) (1977)).

In any event, the district court's ruling in this respect has been overtaken by events. The agency received thirteen public comments after the publication of the Final EA, most of which duplicated comments filed in the rulemaking and received in response to the initial EA and proposed rule. 70 Fed. Reg. at 18,252-18,253 (Addendum 4-5). The agency addressed those comments prior to issuing a FONSI on April 8, 2005. Id. at 18,252. The agency also addressed additional issues raised in R-CALF's Complaint which were never submitted as part of the comment process (although R-CALF was one of the many organizations which participated in the comment process).

In light of the publication of the FONSI, the Secretary issued an Affirmation of Final Rule which ratifies the final rule. 70 Fed. Reg. 18,252 (Addendum 4). Any procedural objections that R-CALF might raise as to the timing of the agency's NEPA compliance can no longer serve as the basis for an order barring implementation of the rule. See Safari Aviation v. Garvey, 300 F.3d 1144, 1150 (9th Cir. 2002).

2. The Risk Analysis In The Final Environmental Assessment Was Not Flawed

The district court incorrectly concluded that the EA was required to provide a quantitative assessment of the risk of introducing BSE and relied on an outdated risk analysis. That ruling has no greater substance than the court's holding that the Secretary was required to represent his ultimate determination of risk in quantitative form. When deciding whether to issue a FONSI or prepare an EIS for a particular agency action, the agency only needs to decide whether the impact of the action will be significant; nothing in NEPA or its implementing regulations requires the agency to engage in quantitative rather than qualitative assessments of risk. See 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1501.4, 1508.27. The "hard look" requirement of NEPA mandates only that there be a "reasonably thorough discussion of the significant aspects of the probable environmental consequences." Block, 690 F.2d at 761. "NEPA does not demand that every federal decision be verified by reduction to mathematical absolutes for insertion into a precise formula." Sierra Club v. Lynn, 502 F.2d 43, 61 (5th Cir. 1974). All that can be demanded is a disclosure sufficient to enable the agency to make an informed decision and take environmental issues into account. See Bicycle Trails Council v. Babbitt, 82 F.3d 1445, 1464 (9th Cir. 1996) (EA on closing trails to bicycles could rely on comments of hikers and others regarding user conflicts; agency

did not have to carry out a "survey or study performed scientifically to determine how many conflicts occur and how and why they occur."); Northern Plains Resource Council v. Lujan, 874 F.2d 661, 666 (9th Cir. 1989) (NEPA "merely requires that [the agency] estimate the impacts" of a proposed project and its alternatives).

Moreover, because review of an agency's NEPA compliance is deferential, "an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive." Marsh v. Oregon Natural Resources Council, 490 U.S. 360, 378 (1989). In developing the rule and the EA, the USDA relied on a comprehensive analysis of the risk that included both qualitative and quantitative components that included the Harvard-Tuskegee Study and Canada's 2002 quantitative risk assessment. 70 Fed. Reg. at 464. USDA, therefore, took the requisite "hard look" at the potential impacts of the rule - namely whether allowing the importation of Canadian cattle and beef under the terms of the rule risked the introduction of BSE into the United States - and concluded that there were no significant impacts. NEPA requires no more. See Greenpeace Action, 14 F.3d at 1332.

Nor, contrary to the district court's understanding, did the agency rely on an outdated risk assessment. A transcription error in the FEA released on January 4, 2005, resulted in the

omission of several references to an updated agency risk analysis. The agency corrected those errors in its citations, published a new Federal Register notice of the availability of the corrected FEA on January 21, 2005, and extended the public comment period on the corrected FEA an additional 14 days to February 17, 2005. 70 Fed. Reg. at 3184; see also 70 Fed. Reg. at 18,252 (Addendum 4). The agency had time to consider the comments before the effective date of the final rule and any error associated with the transcription problems was harmless.

3. The Agency Was Not Required To Consider Other Impacts Of Importing Canadian Cattle

The district court incorrectly concluded the EA should have analyzed the impacts from the potential increase in truck traffic and holding of feeder cattle awaiting slaughter. No commenter raised these concerns, and, as the Supreme Court has explained, a commenter that does not raise such an objection to an EA during the comment period "forfeit[s]" the objection and cannot raise it in subsequent litigation. Department of Transp. v. Public Citizen, 124 S. Ct. 2204, 2214 (2004). It is "incumbent upon intervenors who wish to participate [in the NEPA process] to structure their participation so that it is meaningful, so that it alerts the agency to the intervenors' position and contentions." Vermont Yankee Nuclear Power v. Natural Resources Defense Council, 435 U.S. 519, 553 (1978). Even commenters who make "cryptic and obscure reference to matters that 'ought to be'

considered and then, after failing to do more to bring the matter to the agency's attention, seek[] to have that agency determination vacated" on the grounds that the agency did not consider those matters cannot prevail on those arguments in court. Id. at 554.

Because no commenter - including R-CALF - addressed the potential increase in truck traffic and holding of cattle awaiting slaughter during the comment periods on the original and final EAs, R-CALF may not raise these issues for the first time in litigation as grounds for attacking the agency's NEPA compliance. Public Citizen, 124 S. Ct. at 2214; see also Vermont Yankee, 435 U.S. at 554-55; Citizens for Clean Air v. EPA, 959 F.2d 839, 847 (9th Cir. 1992) (agency was not arbitrary and capricious in disregarding comments that were "more specific than were those in Vermont Yankee" but still unsupported by data).

Nor is this a case where the agency might have to consider additional issues because the EA's flaws are "so obvious that there is no need for a commentator to point them out specifically in order to preserve its ability to challenge a proposed action." Public Citizen, 124 S. Ct. at 2214. The Secretary considered the obvious factors necessary to decide whether to prepare an EIS - it took a hard look at whether designating Canada as a minimal risk region, given the numerous safety measures required by the rule, risked the introduction of BSE into the United States.

The district court's reliance on Public Citizen v.

Department of Transp., 316 F.3d 1002, 1023 (9th Cir. 2003), overruled by Department of Transp. v. Public Citizen, 541 U.S. 752 (2004), is misplaced. In Public Citizen, unlike in this case, commenters asked the agency to evaluate the environmental impacts from additional truck traffic. 316 F.3d at 1023.

Moreover, the district court here essentially reasoned that the Secretary had to consider the alleged additional truck trips because the rule was a but-for cause of the trips - the trips would not occur unless the Secretary lifted the moratorium on importing Canadian cattle. See ER 127-128 (Op. at 20-21). However, in Public Citizen, the Supreme Court explained that even where a commenter has not forfeited an objection, a "'but for' causal relationship is insufficient to make an agency responsible for a particular effect under NEPA" and that whether an agency must consider additional information must be "based on the usefulness of any new potential information to the decisionmaking process." 124 S. Ct. at 2215. Absent an explanation of how the agency might have changed its rule in response to an evaluation of the impacts from additional truck traffic, the district court abused its discretion in concluding that R-CALF was likely to succeed on the merits of its assertion that the Secretary should have considered those impacts. See id. at 2215-16; see also Kootenai Tribe v. Veneman, 313 F.3d 1094, 1126 (9th Cir. 2002).[2]

[2] Even if R-CALF's trucking and cattle holding objections were properly before the agency, they can no longer serve to

4. The Agency Was Not Required To Prepare an EIS

The district court criticized the Secretary for not preparing an EIS. ER 128 (Op. at 21). However, an EIS is only required if the proposed rule would have a significant impact on the environment. See 40 C.F.R. § 1501.4. The district court's objections on this ground mirror the errors reflected in its decision to set aside the Secretary's determination that continuing to prohibit importation of Canadian beef and cattle under 30 months old is not necessary to avoid the introduction of BSE.

The district court was similarly wide of the mark in declaring that "[d]espite public comment requesting that APHIS prepare an EIS, no EIS was prepared." ER 127 (Op. at 20). But the agency is not required to prepare an EIS because a commenter requests one. See, e.g., N. Am. Wild Sheep v. USDA, 681 F.2d 1172, 1182 (9th Cir. 1982) (public opposition to agency action is not a "controversy" under 40 C.F.R. § 1508.27(b)(4) necessitating an EIS). The agency fulfilled its NEPA obligations by

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invalidate USDA's NEPA compliance because USDA incorporated concerns about the alleged impacts in its FONSI and concluded that those impacts are not significant. 70 Fed. Reg. at 18,260-18,262 (Addendum 12-14). The impacts from trucking and feedlot confinement are not significant because, among other things, the 35,000 additional truck trips that R-CALF predicted would amount to an increase of only 1/3 of one percent at border crossings where Canadian cattle are likely to come into the country, Canadian feeder cattle will be, at most, only 1.8 to 2.2 percent of fed cattle marketed annually in the United States, and neither the trucks nor the cattle are expected to concentrate at any border crossings or feedlots. Ibid.

considering the impacts of its proposed action as well as the substance of the comments it received and determining that the impacts from the rule are not significant.

IV. BECAUSE THE SECRETARY PROPERLY DETERMINED THAT AN ABSOLUTE BAN ON IMPORTS IS NOT REQUIRED TO PREVENT INTRODUCTION OF BSE, THE PRELIMINARY INJUNCTION DOES NOT SERVE THE PUBLIC INTEREST AND PROTECTS NO LEGITIMATE INTEREST OF THE PLAINTIFF.

The Secretary determined that an absolute ban on imports is not required to preclude introduction of BSE. The entry of the preliminary injunction is predicated upon the rejection of that determination. Because the district court's analysis of the regulation constitutes clear legal error, its conclusion that an injunction is required to protect the interests of plaintiffs and the public is equally without basis.

The district court's suggestion that an injunction is necessary to guard against a threat to human health is devoid of any basis. There are no probable or confirmed cases of vCJD from consuming Canadian beef, either before or after May 2003. Indeed, the evidence indicates that there is a "substantial species barrier that may protect humans from widespread illness due to BSE," 70 Fed. Reg. at 462, and research indicates that the amount of "infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle," ER 63 (Engeljohn Dec. ¶ 15).

Indeed, R-CALF's own members have purchased the same

Canadian cattle that it characterizes as unsafe in this lawsuit, taking advantage of prices that are artificially depressed as a result of the injunction. See, e.g., Beth Gorham, The Canadian Press (Mar. 7, 2005) ("R-CALF bought cheap cows in Canada; group's president says it's no 'big deal'").

Although the district court gave great weight to possible economic harm to ranchers that might occur under the new rule, it ignored the countervailing harms to other sectors of the economy that flow from the injunction. For example, the district court speculated, without apparent basis, that entry of Canadian beef into the U.S. will cause other countries to close (or keep closed) their borders to American cattle and beef, resulting in economic harm. ER 132 (Op. at 25). The court gave no weight, however, to the fact that USDA's rule would result in a net benefit to the U.S. economy. See ER 90-91 (Fillo Dec. ¶ 8); see also 70 Fed. Reg. at 518 (discussing the "positive impacts" the rule would have for the "wider economy").

The district court also believed that once Canadian imports were allowed to "intermingle" with U.S. beef, it would result in a "stigma" for American beef products in the minds of consumers, from which the U.S. beef industry could never recover. ER 132-133 (Op. at 25-26). That unfounded conclusion is directly at odds with the Secretary's explanation that "[t]here has been no evidence that domestic consumers" have stopped eating beef even following limited resumption of the importation of Canadian

boneless meat in August 2003. 70 Fed. Reg. at 522; see also ER 87-88 (Fillo Dec. ¶ 4). To the contrary, "all market reports indicate that consumer demand for beef remains strong . . . [and] surveys of U.S. consumers in January 2004 . . . indicated that 97 percent of consumers were aware of BSE and a record 89 percent were confident in the safety of domestic beef on the market. That confidence level increased to 91 percent in February surveys." 70 Fed. Reg. at 522.

The Secretary, unlike the district court, must deal with our trading partners. See 7 U.S.C. § 8301(5) ("[R]egulation by the Secretary and cooperation by the Secretary with foreign countries . . . are necessary to prevent and eliminate burdens on . . . foreign commerce [and] to protect the . . . economy . . . and welfare of the people of the United States."). The United States and Canada have cooperated closely in pursuing the shared goal of avoiding introduction and dissemination of BSE, and Canada has taken numerous steps to ensure that importation of its cattle and beef can resume without presenting any threat to health and safety. Remarkably, the district court refused Canada permission to file a brief as amicus curiae before enjoining exports from that nation (ER 422-423), and its decision wrongly discounts the importance of the coordinated safety efforts that remove any basis for the injunction.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed and the preliminary injunction vacated.

Respectfully submitted,

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APRIL 2005

CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(a)(7)(B) AND NINTH CIRCUIT RULE 32-1

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) and (C) and Ninth Circuit Rule 32-1, I certify that the attached Brief for Appellees is monospaced, has 10.5 or fewer characters per inch and contains no more than 13,988 words.

JOSHUA WALDMAN
Counsel for Appellants

CERTIFICATE OF SERVICE

I hereby certify that pursuant to Fed. R. App. P. 25(d)(2) and 31(b) and Ninth Circuit Rule 30-1.2, on April 11, 2005, I caused two copies of the foregoing brief and 1 copy of the Excerpts of Record to be served by Federal Express overnight delivery on the following:

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I also hereby certify, pursuant to Fed. R. App. P. 25(d)(2) and Ninth Circuit Rules 30-1.2 and 31-1, that on April 14, 2005, I filed an original and 15 copies of the foregoing brief and five copies of the Excerpts of Record by causing them to be sent by Federal Express overnight delivery to:

MS. CATHY CATTERSON
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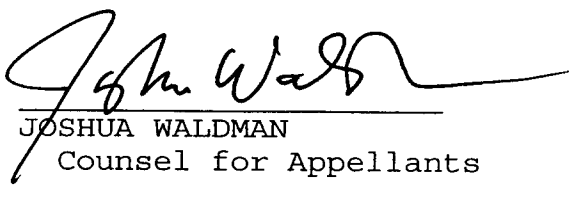

JOSHUA WALDMAN
Counsel for Appellants

STATEMENT OF RELATED CASES

Counsel is aware of only one pending related case within the meaning of Ninth Circuit Rule 28-2.6. That case, No. 05-35214, is an appeal by the National Meat Association of the preliminary injunction and of the district court's denial of its motion to intervene.

ADDENDUM

Regulatory Flexibility Act

As Acting Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this rulemaking will not have a significant economic impact on a substantial number of small entities because it primarily affects Federal employees.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this amendatory rulemaking does not contain information collection requirements that require the approval of the Office of Management and Budget.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. chapter 25, subchapter II), the final rule will not significantly or uniquely affect small governments and will not result in increased expenditures by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more (as adjusted for inflation) in any one year.

Congressional Review Act

The Office of Government Ethics has determined that this amendatory rulemaking is a nonmajor rule under the Congressional Review Act (5 U.S.C. chapter 8) and will submit a report thereon to the U.S. Senate, House of Representatives and General Accounting Office in accordance with that law at the same time this rulemaking document is sent to the Office of the Federal Register for publication in the **Federal Register**.

Executive Order 12866

In promulgating these technical amendments, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. These amendments have not been reviewed by the Office of Management and Budget under that Executive order, since they are not deemed "significant" thereunder.

Executive Order 12988

As Acting Director of the Office of Government Ethics, I have reviewed this final amendatory regulation in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

List of Subjects

5 CFR Part 2634

Certificates of divestiture, Conflict of interests, Financial disclosure, Government employees, Penalties, Privacy, Reporting and recordkeeping requirements, Trusts and trustees.

5 CFR Part 2635

Conflict of interests, Executive branch standards of ethical conduct, Government employees.

Approved: March 4, 2005.

Marilyn L. Glynn,

Acting Director, Office of Government Ethics.

■ For the reasons set forth in the preamble, the Office of Government Ethics is amending 5 CFR parts 2634 and 2635 as follows:

PART 2634—EXECUTIVE BRANCH FINANCIAL DISCLOSURE, QUALIFIED TRUSTS, AND CERTIFICATES OF DIVESTITURE

■ 1. The authority citation for part 2634 continues to read as follows:

Authority: 5 U.S.C. App. (Ethics in Government Act of 1978); 26 U.S.C. 1043; Pub. L. 101–410, 104 Stat. 890, 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990), as amended by Sec. 31001, Pub. L. 104–134, 110 Stat. 1321 (Debt Collection Improvement Act of 1996); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2634.304 [Amended]

■ 2. Section 2634.304 is amended by:
■ a. Removing the dollar amount "$285" in paragraphs (a) and (b) and in example 1 following paragraph (d) and adding in its place in each instance the dollar amount "$305";
■ b. Removing the dollar amount "$114" in paragraph (d) and in examples 1 and 2 following paragraph (d) and adding in its place in each instance the dollar amount "$122"; and
■ c. Removing the dollar amount "$285" in examples 3 and 4 following paragraph (d) and adding in its place in each instance the dollar amount "$305".

PART 2635—STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE EXECUTIVE BRANCH

■ 3. The authority citation for part 2635 continues to read as follows:

Authority: 5 U.S.C. 7301, 7351, 7353; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306.

§ 2635.204 [Amended]

■ 4. Section 2635.204 is amended by:
■ a. Removing the dollar amount "$285" in paragraph (g)(2) and in examples 1 and 2 (in the latter of which it appears twice) following paragraph (g)(6) and adding in its place in each instance the dollar amount "$305"; and
■ b. Removing the dollar amount "$570" in example 2 following paragraph (g)(6) and adding in its place the dollar amount "$610".

[FR Doc. 05–4879 Filed 3–10–05; 8:45 am]
BILLING CODE 6345–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 94 and 95

[Docket No. 03–080–6]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Partial Delay of Applicability

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; partial delay of applicability.

SUMMARY: The amendments in this final rule delay until further notice the applicability of certain provisions of the rule entitled "Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities," published in the **Federal Register** on January 4, 2005, 70 FR 460–553. That rule was scheduled to amend the regulations in 9 CFR parts 93, 94, 95, and 96, effective March 7, 2005, to establish a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States via live ruminants and ruminant products and byproducts and to add Canada to this category. That rule included conditions for the importation of certain live ruminants and ruminant products from such regions.

DATES: Effective March 7, 2005.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION: On January 4, 2005, we published a final rule in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) that establishes a category of regions that present a minimal risk of introducing

bovine spongiform encephalopathy into the United States via live ruminants and ruminant products and byproducts and that adds Canada to this category. The rule also establishes conditions for the importation of certain live ruminants and ruminant products from such regions. The rule was scheduled to become effective on March 7, 2005.[1]

Pursuant to an announcement by the Secretary of Agriculture on February 9, 2005, this document delays the applicability of the provisions in that rule as they apply to the importation from Canada of the following commodities when derived from bovines 30 months of age or older when slaughtered: (1) Meat, meat food products, and meat byproducts other than liver;[2] (2) whole or half carcasses; (3) offal; (4) tallow composed of less than 0.15 percent insoluble impurities that is not otherwise eligible for importation under 9 CFR 95.4(a)(1)(i); and (5) gelatin derived from bones of bovines that is not otherwise eligible for importation under 9 CFR 94.18(c).

If the courts allow the January 4, 2005, rule to go into effect while this delay of applicability is in effect, the commodities listed above that are derived from bovines less than 30 months of age when slaughtered must be accompanied to the United States by certification that (1) the age requirement has been met and (2) the commodity was processed in an establishment inspected by the Canadian Food Inspection Agency (CFIA) that operates in compliance with an approved CFIA program to prevent commingling of ruminant products eligible for export to the United States with ruminant products ineligible for export to the United States. Such certification must be made by a full-time salaried veterinary officer of Canada, or by a veterinarian designated and accredited by the Canadian Government, provided the certification is endorsed by a full-time salaried veterinary officer of Canada who represents that the veterinarian issuing the certification was authorized to do so.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the Department's implementation of this action without opportunity for public comment is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and 553(d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The delay of applicability is necessary to give Department officials the opportunity for further review and consideration of the specified provisions. Given the scheduled effective date of those provisions, seeking prior public comment on this delay would have been impractical, as well as contrary to the public interest, in the orderly promulgation and implementation of regulations.

[1] On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of APHIS' January 4, 2005, final rule is preliminarily enjoined.

[2] In accordance with an August 8, 2003, announcement by the Secretary of Agriculture, since August 2003 APHIS has issued permits for the importation into the United States from Canada of certain fresh or frozen liver from bovines of any age.

List of Subjects

9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 95

Animal feeds, Hay, Imports, Livestock, Reporting and recordkeeping requirements, Straw, Transportation.

■ Accordingly, we are amending 9 CFR parts 94 and 95 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE-FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 2. Section 94.19 is amended by adding notes at the end of paragraphs (a), (b), and (f) to read as follows:

§ 94.19 Restrictions on importation from BSE minimal-risk regions of meat and edible products from ruminants.

* * * * *

(a) * * *

Note to paragraph (a): The applicability of paragraph (a) to meat, meat byproducts other than liver, and meat food products when such commodities are derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

(b) * * *

Note to paragraph (b): The applicability of paragraph (b) to whole or half carcasses derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

(f) * * *

Note to paragraph (f): The applicability of paragraph (f) to gelatin derived from the bones of bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

PART 95—SANITARY CONTROL OF ANIMAL BYPRODUCTS (EXCEPT CASINGS), AND HAY AND STRAW, OFFERED FOR ENTRY INTO THE UNITED STATES

■ 3. The authority citation for part 95 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 4. Section 95.4 is amended by adding notes at the end of paragraphs (f) and (g) to read as follows:

§ 95.4 Restrictions on the importation of processed animal protein, offal, tankage, fat, glands, certain tallow other than tallow derivatives, and serum due to bovine spongiform encephalopathy.

* * * * *

(f) * * *

Note to paragraph (f): The applicability of paragraph (f) to tallow derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

(g) * * *

Note to paragraph (g): The applicability of paragraph (g) to offal derived from bovines that were 30 months of age or older when slaughtered is delayed indefinitely.

* * * * *

Done in Washington, DC, this 8th day of March 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 05–4917 Filed 3–10–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19470; Directorate Identifier 2003–NM–268–AD; Amendment 39–13997; AD 2005–05–08]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100B SUD, –300, –400, and –400D Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

Federal Register

Friday,
April 8, 2005

Part VII

Department of Agriculture

Animal and Plant Health Inspection Service

9 CFR Part 93, et al.
Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule; Final Rule

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 93, 94, 95, and 98

[Docket No. 03–080–7]

RIN 0579–AB73

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities; Finding of No Significant Impact and Affirmation of Final Rule

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of final rule.

SUMMARY: We are publishing a finding of no significant impact for a final rule concerning bovine spongiform encephalopathy minimal risk regions published January 4, 2005, and, based on that finding, we are affirming the provisions of the final rule. The finding of no significant impact is based on an environmental assessment that documented our review and analysis of potential environmental impacts associated with the final rule and our review of issues raised by the public regarding the environmental assessment. Together, the environmental assessment and our review of the issues raised provide a basis for our conclusion that the provisions of the final rule will not have a significant impact on the quality of the human environment and support our affirmation of the final rule.

DATES: The final rule published January 4, 2005 (70 FR 460), with a partial delay of applicability published March 11, 2005 (70 FR 12112), was effective March 7, 2005. This affirmation of the final rule is effective April 8, 2005.

ADDRESSES: The environmental assessment on which this finding of no significant impact is based may be accessed by any of the following methods:

- On the EDOCKET Web site at *http://docket.epa.gov/edkfed/do/EDKStaff CollectionDetailView?objectId=0b0007d48055a20d.*
- On the APHIS Web site at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*
- In the APHIS Reading Room in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.
- You may request paper copies of the environmental assessment and the finding of no significant impact by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the titles of these documents when requesting copies.

FOR FURTHER INFORMATION CONTACT: Dr. Karen James-Preston, Director, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–4356.

SUPPLEMENTARY INFORMATION:

Background

On November 4, 2003, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** and requested comment on a proposed rule (68 FR 62386–62405, Docket No. 03–080–1) to amend the regulations regarding the importation of animals and animal products to recognize a category of regions that present a minimal risk of introducing bovine spongiform encephalopathy (BSE) into the United States via live ruminants and ruminant products, and to add Canada to this category. The proposed rule also included provisions for the importation of certain live ruminants and ruminant products and byproducts from Canada under certain conditions. Also on November 4, 2003, we made available for public comment an environmental assessment (EA) regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts under the conditions of the proposed rule. We carefully considered all comments that addressed the EA, along with those that addressed the proposed rule itself.

On January 4, 2005, we published in the **Federal Register** (70 FR 460–553, Docket No. 03–080–3) a final rule to the proposed rule, to become effective March 7, 2005.[1]

Also in the January 4, 2005, issue of the **Federal Register**, we published a notice (70 FR 554, Docket No. 03–080–4) announcing the availability of, and requesting comments on, a final EA regarding the potential impact on the quality of the human environment due to the importation of ruminants and ruminant products and byproducts from Canada under the conditions specified in the final rule. APHIS' review and analysis of the potential environmental impacts associated with those importations were documented in the final EA, titled "Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products from Canada into the United States, Final Environmental Assessment (December 2004)." We announced that the EA would be available to the public for review and comment until February 3, 2005.

We became aware, however, that the version of the EA that was made available on January 4, 2005, contained some transcription errors that resulted in the omission of several references to an updated APHIS risk analysis regarding the final rule, as well as the incorrect formatting of several source citations. We corrected those errors and, on January 21, 2005, published a notice in the **Federal Register** (70 FR 3183–3184, Docket No. 03–080–5) announcing the availability to the public of the corrected EA and extending the comment period on the EA until February 17, 2005.

We reviewed and considered all issues raised by commenters on the final EA. Of the issues raised by the commenters, some addressed the potential effects of the rule on the environment, while others addressed issues unrelated to such potential effects. Most of these issues had been raised by commenters on the proposed rule and had been previously considered and addressed in our final rule and supporting analyses.

Additionally, shortly after issuance of the final rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (R–CALF), filed a complaint challenging the rule in the United States District Court for the District of Montana. In that complaint, R–CALF raised several issues regarding the EA that it had not included in either its comments on the proposed rule or in any comment on the final EA. In addition, no other commenter on the EA raised those potential environmental impact issues. Nonetheless, we addressed those issues in our finding of no significant impact (FONSI), discussed below.

We carefully considered environmental issues throughout the rulemaking. Based on the EA and on our review of the comments received on the original and final EAs, on the proposed rule, and in litigation, we have determined that the provisions of our January 4, 2005, final rule will not

[1] On March 11, 2005, the Department published a document in the **Federal Register** (70 FR 12112–12113, Docket No. 03–080–6), effective March 7, 2005, that delayed until further notice the applicability of certain provisions of the final rule. On March 2, 2005, Judge Richard F. Cebull of the U.S. District Court for the District of Montana ordered that the implementation of the final rule is preliminarily enjoined.

significantly impact human health or the environment, and that there is no basis in the comments we received and the issues that have been raised to alter the rule. Therefore, we are affirming the final rule as published.

Our FONSI is included in this document under the heading "Bovine Spongiform Encephalopathy: Minimal-Risk Regions and Importation of Commodities (Final Rule; APHIS Docket No. 03–080–3), Finding of No Significant Impact." The FONSI includes a discussion of the comments received on the final EA. The EA and FONSI may also be accessed by any of the means listed above under the heading **ADDRESSES**.

The EA and FONSI have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities (Final Rule; APHIS Docket No. 03–080–3)

Finding of No Significant Impact

United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export, Technical Trade Services, 4700 River Road, Unit 38, Riverdale, MD 20737

This finding concludes the environmental assessment process undertaken for the rulemaking, Bovine Spongiform Encephalopathy; Minimal-Risk Regions and Importation of Commodities ("MRR rule"). An environmental assessment ("EA"), dated October 2003, was prepared for this rulemaking and it was made available to the public for comment on November 4, 2003. Comments on the EA were received and carefully considered. A final EA was completed and it was made available to the public on January 4, 2005, for a 30-day comment period. On January 21, 2005, a corrected final EA was made available to the public and the comment period was extended for an additional 14 days until February 17, 2005. The corrected final EA had no changes or additions to the version issued on January 4, 2005, other than some specific references to the latest risk analysis for the MRR rule that had been inadvertently omitted from the final EA. This finding summarizes and incorporates by reference the final EA.

Thirteen comments were received in response to our request for comments on the final EA. One was submitted by a state farm bureau federation with certain specific suggestions. This comment counseled caution in implementing the rule for the following reasons. It pointed to the four confirmed cases of bovine spongiform encephalopathy (BSE) in cows of Canadian origin particularly the most recent diagnosis in a cow that was determined to have been born after implementation of a feed ban in Canada—and recommended that USDA confirm that the Canadian feed ban is being effectively enforced before resuming imports of Canadian cattle under 30 months of age and beef from such younger cattle. Additionally, the comment requested that an effective feed ban have been in place in Canada for a full 8 years before cattle over 30 months of age, and meat from such cattle, are allowed to be imported into the United States. It recommended further review of Canada's surveillance program and asked whether the current level of surveillance in Canada is adequate. The comment supported the animal identification provisions in the rule and recommended that appropriate steps be taken to ensure that all imported cattle were slaughtered before 30 months of age. Finally, the comment noted concerns, which we believe are outside the scope of the environmental assessment, about consumer confidence, our ability to regain access to export markets, and potential impacts on producer returns.

One comment, filed by an individual consumer of beef products who asserted he was not associated with any cattle production or processing business, raised five concerns or issues. These included that there was no quantitative risk assessment in the EA, concern about the duration and effectiveness of Canada's feed ban, concern about the tissues defined as specified risk materials (SRMs) under international standards, concern that public health risk was not adequately analyzed in light of recent diagnoses of BSE in Canada and the levels of feed ban compliance and surveillance in that country, and, finally, a recommendation that an environmental impact statement be completed to study the effect of BSE and TSE disease agents in soil, water, air, and the food chain.

Eight comments—one from a South Dakota organization, one from an Oregon organization, and six from individuals, including an assistant state veterinarian—raised a generally similar array of concerns. The thrust of these eight comments is that the commenters believe the risk of introducing BSE into the United States weighs against implementation of the rule. The comments noted support for maintaining the current prohibitions on imports of live animals and beef products from Canada, concerns about the effect of importation into the United States of Canadian cattle and cattle products on U.S. export markets, concern about the effectiveness of the Canadian feed ban and the adequacy of Canada's surveillance program, concerns about feeding animal protein of any kind to cows or sheep, a recommendation for country-of-origin labeling, and support for testing for BSE all cattle of Canadian origin that are in the United States. Again, certain of these issues are outside the scope of the EA. Several of the comments also raised questions about the implications of the most recently confirmed BSE-positive animals in Canada on January 2 and January 11, 2005, including the fact that one of these animals was born shortly after implementation of the Canadian feed ban in 1997.

A comment from a pharmaceutical association noted the importance of animal-derived materials in numerous products. This comment was received on February 24, 2005, 7 days after the close of the extended comment period for the final EA. Nevertheless, because, as the commenter pointed out, it had commented in a timely fashion on the proposed rule and its EA comment was intended to update its recommendations based on recent developments, we will respond to this comment. The comment supported the need to revise what it termed the "binary system" of BSE classification of countries and the adoption of what it termed a science-based approach to identifying minimal-risk regions for BSE as outlined in the rule. The comment, therefore, supported implementation of the rule. It recommended permanently identifying cattle from Canada and distinguishing Canadian and U.S.-origin cattle for the sourcing of bovine raw materials, which would allow companies to make sourcing decisions to satisfy BSE regulatory requirements in the countries to which these companies would ship their products. The association supported the implementation of a national animal identification system.

One comment took issue with the notation in the final EA that alkaline hydrolysis tissue digesters were a preferred method of disposal for BSE-contaminated carcasses. It took issue with that conclusion and suggested the commenter's validated protocol and

process for enzymatic prion degradation was perhaps equally effective. We acknowledge this comment and would welcome more information and data regarding this technology. It is our view, however, that it does not raise an issue that requires discussion in this document. One comment urged the lifting of the prohibitions on camelids because camelids have no demonstrated history of being susceptible to any type of TSE and because these animals are not used for human consumption. We agree with this comment and note that the MRR rule so provided.

Of the issues raised by the commenters, many concerned topics other than the potential effects of the rule on the environment (for example, comments regarding country-of-origin labeling, market access, and consumer confidence). These issues had been raised by commenters on the proposed rule and were considered and addressed by APHIS in its final rule and supporting analyses. Likewise, most of the commenters who did address the potential effects of the rule on the environment raised issues that had already been raised and addressed at considerable length in the final rule and supporting analyses. This fact illustrates the substantial identity of the central animal and public health issues of the rule and the issues evaluated in the environmental assessments.

It is important to note that issues raised in relation to the two most recent BSE-positive cows in Canada on January 2 and January 11, 2005, will be discussed below. Certain commenters observed that these incidents would call into question the effectiveness and adequate duration of the Canadian feed ban. Because these incidents occurred either after or immediately before the publication of the final EA, we welcome the opportunity to respond in this document.

On January 4, 2005, APHIS issued a final rule to amend regulations regarding the importation of animals and animal products to establish a category of regions that present a minimal-risk of introducing BSE into the United States by way of live ruminants and ruminant products and byproducts, and to add Canada to that category. (70 FR 460–553.) The final rule also established conditions for the importation of certain live ruminants and ruminant products and byproducts from minimal-risk regions. Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture may prohibit or restrict the importation or entry of any animal, article, or means of conveyance, or use of any means of conveyance or facility, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock. (7 U.S.C. 8303.) The MRR rule will regulate the importation of ruminants and ruminant products and byproducts from Canada in a manner that prevents the introduction of BSE into the United States.

The rule defines a BSE minimal-risk region as one that:

1. Maintains, and, in the case of regions where BSE was detected, had in place prior to the detection of BSE in an indigenous ruminant, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:

- Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;
- Surveillance for BSE at levels that meet or exceed recommendations of the World Organization for Animal Health (Office International des Epizooties or OIE) for surveillance for BSE; and
- A ruminant-to-ruminant feed ban that is in place and is effectively enforced.

2. In regions where BSE was detected, conducted an epidemiological investigation following detection of BSE sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and continues to take such measures.

3. In regions where BSE was detected, took additional risk mitigation measures, as necessary, following the BSE outbreak based on risk analysis of the outbreak, and continues to take such measures.

These standards are based upon, and are consistent with, international guidelines issued by OIE. For a full analysis and discussion of these standards, see APHIS' November 4, 2003, proposed rule (68 FR 62388–62389) (please note that some revisions were made to the wording of the proposed standards in the final rule) and the update to our risk analysis.[2]

APHIS conducted a comprehensive examination and evaluation of all the relevant risk factors in determining whether Canada qualified as a BSE minimal-risk region. A complete discussion of this evaluation can be found in the risk analysis.[3] In summary, APHIS determined that Canada met the standards for a BSE minimal-risk region because:

1. Canada has implemented comprehensive, effective measures for preventing BSE introduction and the potential for spread within Canada in order to minimize the possibility that infected ruminants, ruminant products, byproducts, or contaminated feedstuffs enter the country. The potential for introduction of the BSE agent into Canada has been limited by import restrictions on meat-and-bone meal (MBM) and live animals. Canada's Animal Disease and Protection Regulations (1978) and Health of Animals Regulations (1991) prohibited importation of MBM from countries other than the United States and, later, from Australia and New Zealand. These rules were first initiated in response to foot-and-mouth disease and later extended to address BSE issues. Canada has not imported live cattle from the United Kingdom (UK) since 1990. In 1994, an import ban was imposed on all countries where BSE had been detected in native cattle, and from 1996 live cattle could only be imported from countries that Canada designated as free from BSE following a comprehensive risk assessment. After detection of BSE in an imported animal in 1993, Canada traced and destroyed and incinerated or repatriated all surviving cattle imported from the UK.

2. Canada has an adult cattle population of approximately 5.5 million cattle older than 24 months of age. The 2004 OIE Code, Appendix 3.8.4, references adult cattle populations as those greater than 30 months and recommends examining at least 300 samples per year from high-risk animals in a country with an adult cattle population of 5 million, or 336 samples per year in a country with an adult cattle population of 7 million. Even though the adult cattle population in Canada is defined as greater than 24 months of age and OIE defines it as greater than 30 months, Canada has met or exceeded this level of surveillance for the past 7 years, thus exceeding the OIE guidelines. Since 1992, the surveillance has been targeted surveillance, with samples obtained from adult animals exhibiting some type of clinical signs or considered high risk for other reasons that could be considered consistent with BSE. From January 2004 through March

[2] See "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004." pp. 2–5. This update can be viewed on the Internet at *http://www.aphis.usda.gov/lpa/issues/bse/bse.html*.

[3] Ibid, pp. 5–18.

2005, over 37,000 samples were obtained. Canadian Food Inspection Agency (CFIA) officials have stated that this surveillance program is designed to detect one case of BSE in one million adult cattle.

3. Since August 4, 1997, Canada has implemented a ruminant-to-ruminant feed ban that is comparable to that existing in the United States and prohibits the feeding of proteins from ruminant species to ruminant animals. Based on CFIA inspections since 2003, virtually 100 percent of Canadian rendering facilities are in compliance with the ruminant-to-ruminant feed ban requirements applicable to this industry. With regard to inspections of feed mills, CFIA reported that, for an annual inspection period of April to March, the fraction of mills reportedly in compliance was 92 percent, 99 percent, and 95 percent for 2002, 2003, and 2004, respectively.[4] CFIA has identified noncompliance of "immediate concern" in fewer than 2 percent of feed mills inspected during 2003–2004. Those instances of noncompliance of "immediate concern" are dealt with rapidly when identified. Noncompliance of "immediate concern" includes situations where direct contamination of ruminant feed with prohibited materials has occurred, as identified through inspections of production documents or visual observation, and where a lack of appropriate written procedures, records, or product labeling by feed manufacturers may expose ruminants to prohibited animal proteins. Accordingly, it is clear that Canada's feed ban is effective.

4. Canada conducted rigorous epidemiological investigations after the BSE cases were detected in May 2003 and December 2003 and after the detections in January 2005.[5] In all but the most recent detection, the cases were animals that were born before the implementation of the feed ban in 1997, with exposure assumed to occur prior to or near the time of the imposition of the feed regulations. The cow in the last detected case was born within a year after implementation of the Canadian feed ban. Although a specific source of infection was not identified, the most likely possibility was the introduction of a low level of infectivity into the animal feed supply originating from an infected animal imported from the UK in the period between 1982 and 1989. These investigations have resulted in the destruction and sampling of a large number of potentially exposed cattle, and results from all testing have yielded no further evidence of infection. CFIA has traced and destroyed the majority of surviving cattle that were birth cohorts of each of the cases of Canadian origin.

5. CFIA imposed new regulations to further strengthen its safeguards against BSE. Measures taken included requiring the removal of bovine SRMs; enhancing enforcement activities associated with the existing cattle identification system; and increasing the level of BSE testing.

Canada has provided comprehensive information throughout this rulemaking regarding its BSE status and the actions it has taken to protect animal and public health and food safety. The most recent Canadian status update can be accessed through the CFIA 2 Web site at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.*

In summary, the essential factors that led us to conclude that Canada qualified as a BSE minimal-risk region include longstanding Canadian import restrictions, an effective ban on the feeding of ruminant protein to ruminants, the quality of Canada's surveillance and monitoring program, and other measures, such as the required removal of SRMs from cattle at the time of slaughter and enhanced enforcement of Canada's existing mandatory cattle identification system.

APHIS has concluded that the animal and public health measures that Canada has in place to prevent BSE, combined with existing U.S. domestic safeguards and additional safeguards provided in the final rule, provide the utmost protection to U.S. consumers and livestock. With respect to Canadian cattle, the MRR rule will allow the importation of:

- Bovines, for immediate slaughter, or for feeding, as long as they are slaughtered at less than 30 months of age;
- Meat from bovines; and
- Certain other products and byproducts, including bovine livers and tongues, gelatin, and tallow.

The final rule provides the following additional requirements for live Canadian feeder cattle that will ensure they are slaughtered before they reach 30 months of age:

- Feeder cattle must be permanently marked with a brand to identify the BSE minimal-risk region of origin before entering the United States. Feeder cattle exported from Canada will be branded with "C/AN";
- Cattle must be individually identified with an ear tag before entering the United States. This ear tag allows the animal to be traced back to the premises of origin (birth herd);
- Information must be included on the cattle's animal health certification, relating to animal identification, origin, destination, and responsible parties;
- Cattle must be moved to feedlots in sealed containers and cannot go to more than one feedlot; and
- SRMs will be removed from Canadian cattle slaughtered in the United States in accordance with FSIS regulations.

Based on our risk analyses, APHIS concluded that the cumulative effect of all of the measures in place in Canada and the United States, and the additional measures imposed by the final rule, is an extremely effective set of interlocking, overlapping and sequential barriers to the introduction and establishment of BSE in the United States.[6] The preceding discussion and conclusions provide the foundation for the finding of no significant impact described below.

The final rule was scheduled to become effective on March 7, 2005. On February 9, 2005, the Secretary of Agriculture announced that the provisions of the final rule allowing the importation of beef products from cattle over 30 months of age would be delayed.[7] On March 2, 2005, the United States District Court for the District of Montana issued a preliminary injunction that enjoined implementation of the MRR rule.

Pursuant to the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), the purpose of an environmental assessment is to provide sufficient information and analysis to agency decision makers to allow them to determine whether the proposed agency action will have a significant effect on the human environment. If a determination is made that the action would have a significant effect on the human environment, the agency is obligated to prepare an environmental impact statement. If a determination is made that the action will not have a significant effect on the human environment, a finding of no significant impact is issued.

The two EAs issued for the MRR rule considered two alternatives: (1) The "No

[4] Canadian Food Inspection Agency (CFIA). Memorandum from Dr. Brian Evans, Chief Veterinary Officer, to Dr. John Clifford, Deputy Administrator, VS, APHIS. July 30, 2004.

[5] Canadian reports of the investigations can be accessed at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/bseesbindexe.shtml.*

[6] See "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004." pp. 25–27.

[7] On March 11, 2005, APHIS published a notice in the **Federal Register** delaying the applicability of the provisions of the rule relating to beef products and byproducts from bovines 30 months of age or older (70 FR 12112).

Action" alternative, which would maintain the continued regulatory prohibition of the importation of ruminants, ruminant products, ruminant by-products from Canada and from any other country or region that could eventually be classified as a BSE minimal-risk region pursuant to the rulemaking and (2) the preferred alternative, which will allow for the importation of certain ruminant products and by-products and certain ruminants, providing the country or region seeking recognition as a BSE minimal-risk region demonstrates that it meets the relevant factors consistent with standards recommended by the OIE.

The environmental issues involved in this rulemaking, including those raised in comments on the two EAs as well as in litigation, are discussed below.

A. The Degree to Which the Action May Affect Public Health or Safety

The introduction of BSE into the United States has the potential to affect both human and animal health. BSE, commonly known as "mad cow disease," is a disease that belongs to a family of mostly very rare diseases known as TSEs. Cases of BSE in cattle were first reported in the UK in 1986. To date, over 95 percent of all known BSE cases worldwide have occurred in the UK. Within cattle herds, BSE is not contagious and does not spread from animal to animal. It is spread to cattle primarily through the consumption of animal feed containing protein from ruminants infected with BSE. In 1996, a new disease, variant Creutzfeldt-Jakob disease or vCJD, was detected in humans and linked to the BSE epidemic in cattle. Consumption of cattle products contaminated with the BSE agent is reported to be the cause of vCJD. Approximately 153 cases of vCJD have been identified worldwide and 95 percent of these cases have been linked to exposure in the UK. When compared with the significant number of cattle exposed to BSE, the relatively small number of cases of vCJD indicates a substantial species barrier that protects humans from widespread illness due to BSE exposure.

As previously discussed, the MRR rule amends APHIS' regulations to allow the importation of certain ruminants, ruminant products and by-products from regions that pose a minimal risk for BSE. The rule will preclude introduction of BSE into the United States and will ensure the protection of domestic livestock and the food supply. The MRR rule is fully consistent with the guidelines and recommendations of the OIE for trade in animals and animal products from BSE-affected countries.

In determining whether it was necessary to continue the prohibitions and restrictions on imports from Canada pursuant to the Animal Health Protection Act, APHIS analyzed the risks associated with such imports. The analysis is consistent with OIE guidelines and the internationally recommended components for animal health import risk analysis. The risk analysis drew on a number of sources of information, including: Previous analyses of risk conducted by APHIS; scientific literature; results of epidemiological investigations; data provided by the Canadian Government; a quantitative analysis of the risk of BSE in Canada; quantitative analyses of the consequences of BSE being introduced into the United States; measures implemented by USDA's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) to protect against human exposure to the BSE agent in the United States; reports by international review teams; and the BSE guidelines adopted by the OIE. The determination to allow imports of certain Canadian ruminants and ruminant products was based on a thorough evaluation of the BSE risk in Canada, the potential for BSE infectivity to be introduced into the United States, the potential spread of BSE in cattle and possible human exposure if BSE infectivity were introduced into the United States, and the likelihood that BSE could become established in the United States.

A great deal is now known about BSE. There is a strong scientific consensus about the BSE agent, the mechanisms for its spread, and the tissues that are most likely to harbor the infective agent. Scientific research, backed by practical experience, has resulted in a defined series of measures that countries can use to keep the BSE agent out of the food and feed chain and thus ensure the safety of animal and public health. APHIS has concluded that such measures are in place in Canada and the United States. The risk analysis contains a comprehensive discussion of the facts and circumstances relevant to Canada's BSE status and of the mitigation measures in place in both Canada and the United States that will ensure that BSE is not introduced into the United States. The critical country-of-origin factors leading to APHIS' conclusion and this finding of no significant impact are:

1. *Import Restrictions*—Canada has implemented effective methods for preventing the introduction of BSE into its herd by restricting the importation of live ruminants and meat-and-bone meal from any country that had not been recognized as BSE-free following a comprehensive risk assessment.

2. *Surveillance*—Canada has been actively monitoring for BSE in its herd since 1992 and has met or exceeded the OIE recommended level of BSE surveillance for the past 7 years. The number of cattle tested annually has steadily increased over the years, and in 2003, approximately 5,700 cattle were tested. In 2004, more than 23,500 animals were tested. In 2005, more than 14,000 samples were tested as of March 23.

3. *Feed Ban*—Canada and the United States implemented substantially identical feed bans simultaneously in 1997 that prohibit the feeding of mammalian protein to ruminants. Canada's feed ban is more stringent than the feed ban in the United States, as it prohibits the use of plate waste and poultry litter in ruminant feed. The Canadian feed ban has been effective and has a strong compliance and enforcement component. It is also important to note that Canada established its feed ban 6 years before identifying its first case of BSE in May 2003.

4. *Epidemiological Investigations*—Canada has the capacity to conduct, and has conducted, rigorous investigations of its BSE findings. These investigations have included trace-outs of cattle that may have been exposed to the same feed sources as infected cattle and of rendered protein products that could have included the tissues from the infected animals. These investigations have been successful due in part to the mandatory cattle identification program in Canada.

5. *Removal of SRMs*—Both Canada and the United States require the removal at slaughter of SRMs—those tissues most likely to harbor the BSE infective agent—and prohibit the use of SRMs in human food.

In addition, there are several biological factors that support the finding herein with specific reference to the importation of live animals and animal products. These factors include: The age of the animal, tissue distribution and infectivity, and feed source and exposure. Our findings with respect to these factors are detailed in the final risk analysis associated with this final rule.[8] Furthermore, as explained in the exposure assessment

[8] See "Analysis of Risk—Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004," pp. 11–17.

component of the risk analysis, our evaluation of slaughter controls in place in both the United States and Canada, rendering inactivation factors, feed manufacturing controls both in the United States and Canada, and of the likelihood that an animal would ingest an infectious dose and would develop the disease provides further support for our finding of no significant impact.

Finally, the additional post-entry mitigation measures imposed by the final rule enhance protection of animal and human health and further ensure that there will be no significant impacts. The MRR rule requires that live cattle under 30 months of age can only enter the United States for immediate slaughter or for feeding and slaughter. Movement of these cattle is carefully controlled by requiring each animal to have permanent identification that identifies its country of origin, and a special permit designed to account for the inventory of cattle consigned to their point of destination. The rule, therefore, ensures that those cattle are identified and remain accounted for through slaughter.

Based on all these factors, APHIS concluded that there was no scientific basis to believe that the importation from Canada of live ruminants (including cattle less than 30 months of age) and ruminant products (including beef products and byproducts) in accordance with the conditions required in the rule pose any risk of introducing BSE into the United States. For all the reasons discussed in section VI.A. of the final EA, the safeguards in place in both the United States and Canada, coupled with the additional risk mitigation measures required in the MRR rule fully protect both animal and public health.

B. The Degree to Which the Effects on the Quality of the Human Environment Are Likely To Be Highly Controversial or the Degree to Which the Possible Effects on the Human Environment Are Highly Uncertain or Involve Unique or Unknown Risks

Controversy exists when substantial questions are raised as to whether an action may cause significant degradation of an environmental factor. In the context of an EA under NEPA, controversy refers not to the existence of public opposition, but to a substantial dispute about the size, nature, or effect of the action. Even if an action is projected to have a controversial effect, the agency nonetheless has the discretion to be guided by the expertise and judgment, as well as the practical experience, of its own experts. There is a presumption in favor of the agency's expert advice and guidance.

In the case of the MRR rule, there is no significant controversy with regard to the science underlying the mitigation measures that form the basis of the rule, and the effectiveness of the mitigation measures that are in place in Canada and the United States or prescribed as additional requirements in this rule. While questions remain about BSE and research continues on BSE as it does for many animal diseases, there is substantial knowledge about the disease and effective mitigation measures, and a solid scientific consensus among animal health experts both in the United States and internationally. Based upon this substantial body of scientific research, field epidemiological investigations and years of practical experience and observations by animal health authorities, very effective measures have been identified to prevent the introduction and spread of BSE and these measures have been put in place in the United States and Canada and are embodied in the MRR rule.

Two principal concerns are expressed in comments filed on the EA in opposition to the MRR rule. First is the perceived risk that BSE would be introduced into domestic cattle and, second, that vCJD could occur as a result of such introduction or through the import of meat products from Canada. APHIS has concluded that the MRR rule will preclude the introduction of BSE and that the comprehensive animal and public health measures in place in Canada and in the United States will prevent these effects from occurring. In this regard, we must note that while APHIS' principal responsibilities encompass animal and plant health, FSIS and the FDA are the agencies principally responsible for public health and food safety. Both of these agencies have implemented regulations to ensure that the BSE agent does not enter either the human or the ruminant food chain.[9] In developing the MRR rule and in preparing the EA, APHIS consulted with both FSIS and FDA.

This rule is based upon and is fully consistent with an international scientific consensus that is embodied in the guidelines and recommendations of the OIE. OIE is the internationally recognized authority on animal health issues and currently has 167 member countries, including the United States and Canada. OIE develops and publishes standards, guidelines and recommendations for international trade in animals and animal products. These standards and guidelines are recognized by the World Trade Organization as the reference international animal health rules for animal diseases and zoonoses and they are codified in the Terrestrial Animal Health Code and the Aquatic Animal Health Code. The standards, guidelines and recommendations are developed by specialist commissions and experts based on the latest and best available scientific research and data and are adopted by consensus of the OIE member countries. The aim of the Terrestrial Animal Health Code is to facilitate the safe international trade of animals and animal products. This is achieved through recommendations on risk management measures for specific diseases to be used by national veterinary authorities or other competent authorities of importing and exporting countries when establishing health regulations for the safe importation of animals and animal products. The aim of the OIE's work in this regard is to avoid the transfer of agents pathogenic for animals and humans, without the imposition of unjustified trade restrictions. With respect to the OIE guidelines for BSE, it is important to note that the OIE does not recommend that an importing country completely ban the importation of live cattle and meat products even when the importing country determines that the exporting country has a high BSE risk status. For the details of the BSE chapter of the Terrestrial Animal Health Code, see *http://www.oie.int/eng/publicat/en_code.htm*.

Many of the 13 commenters on the final EA opposed implementation of the MRR rule out of a concern that BSE would be introduced into the United States, a concern raised in part by the 2 confirmed cases of BSE in Canada in January 2005. These commenters did not elaborate on the basis for their concern or whether they disagreed with the scientific foundation of the MRR rule. On the other hand, some commenters who expressed concerns about the implementation of the MRR rule acknowledged, implicitly or explicitly, the validity of the scientific

[9] See: FSIS' interim final rule published in the **Federal Register** on January 12, 2004, titled "Prohibition on the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (69 FR 1874–1885, FSIS Docket No. 03–025IF,); FDA interim final rule published in the **Federal Register** on July 14, 2004, titled "Use of Materials Derived from Cattle in Human Food and Cosmetics" (69 FR 42255, FDA Docket No. 2004N–0081); FDA's ruminant feed regulations in 21 CFR 589.2000; and an advance notice of proposed rulemaking issued jointly by FDA, FSIS, and APHIS in the **Federal Register** on July 14, 2004, titled "Federal Measures to Mitigate BSE Risks: Considerations for Further Action" (69 FR 42288–42300, FDA Docket No. 2004N–0264, FSIS Docket No. 04–021ANPR, APHIS Docket No. 04–047–1).

approach embodied in the rule but urged the agency to ensure that the measures the agency relies upon have been effectively implemented. For example, the state farm bureau federation urged that USDA "investigate and confirm" that the current feed ban is being effectively enforced prior to opening the border with Canada. Additionally, the federation urged that USDA assess whether Canada's surveillance program is adequate.

Four cases of BSE have been detected in Canadian-origin cattle. The first two positive cases were detected in 2003 and two cases have been detected in 2005. On January 2, 2005, Canada announced that it had confirmed a case of BSE in an 8-year-old dairy cow in Alberta, Canada.

The following week, on January 11, 2005, Canada announced that it had confirmed a case of BSE in a beef cow in Alberta that was born shortly after the implementation of the feed ban in 1997. Because the cow was born shortly after the implementation of the feed ban and, in addition, to determine if there were any previously unidentified potential links, the USDA sent two technical teams to Canada to evaluate the circumstances surrounding these two recent BSE findings. One team, consisting of USDA and FDA officials, was responsible for conducting an in-depth assessment of Canada's feed ban, and the other team focused on the epidemiological investigations of the positive cases.

In preparing the MRR rule, Canada's compliance with the feed ban was thoroughly considered and discussed. Canada implemented its feed ban in 1997 to prohibit the feeding of most mammalian protein to ruminants. Canada's feed ban is virtually identical to the feed ban in place in the United States, except that Canada has extended its ban by prohibiting plate waste and poultry litter from being fed to ruminants. APHIS concluded, based on this thorough assessment, that Canada has had an effective feed ban in place in the rendering, feed manufacturing and livestock industries. (70 FR 467–468, APHIS Docket No. 03–080–3; "Analysis of Risk-Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, December 2004," pp. 7–10; see also BSE in Canada Status Update—March, 2005, which can be found at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.*)

On February 25, 2005, USDA published its assessment of the Canadian feed ban. The team concluded, based on its review of inspection records for the last 3 years and on-site inspections of commercial feed mills and rendering facilities, that Canada has a robust inspection program with strong enforcement, that overall compliance with the feed ban is good, and that the feed ban is effectively reducing the risk of transmission of BSE. (*http://www.aphis.usda.gov/lpa/issues/bse/bse.html.*) The team's report confirmed the APHIS evaluation of Canada's feed ban which supported the MRR rule.

It is important to note that in 1997, BSE had not been detected in North America, and the feed bans implemented by Canada and the United States were precautionary measures. As a result, neither government required that existing feed stocks be recalled. In Canada specifically, the feed ban was implemented with provisions for a phase-in period so that existing stocks of feed material could be depleted. It is likely that the Canadian feed ban took some time to be implemented completely throughout the feed manufacturing industry, as did the United States' feed ban. This would be expected in implementing a new, comprehensive regulatory program.

With respect to the two most recent positive BSE cases, the Canadian government confirmed that the animal identified as positive on January 2nd was exposed to feed rations containing meat and bone meal that was produced prior to the 1997 feed ban. This animal was born in October 1996 and was exposed to rations that contained meat and bone meal in early 1997, before the feed ban was implemented. In the case confirmed on January 11th, the Canadian investigation concluded that BSE may have been transmitted to the affected animal through feed produced shortly after the feed ban was implemented. As described in the previous paragraph, since an extensive change in industry practices cannot be expected to be completed immediately, a finding of BSE in an animal born shortly after the feed ban would not be unexpected and would not be inconsistent with the risk analysis supporting the final rule. (See BSE in Canada Status Update—March, 2005, which can be found at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/200503canadae.shtml.* See also the summary report of the CFIA investigation of the January 2, 2005, case of BSE at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/2investe.shtml* and the summary report of the CFIA investigation of the January 11, 2005, case of BSE at *http://www.inspection.gc.ca/english/anima/heasan/disemala/bseesb/ab2005/3investe.shtml.*)

The possibility of additional BSE positive animals was understood and carefully considered by APHIS in the risk analysis and in our determination that Canada qualifies as a minimal-risk region. In our final rule (70 FR 514), we acknowledged the possibility that additional BSE-infected cattle might exist in Canada and explained the reason for our confidence that the number of such additional infected animals, if any, would be small. First, Canada has not imported ruminant MBM from any country with BSE since 1978. Second, Canada has prohibited the feeding of ruminant MBM to ruminants since 1997, and CFIA has verified high levels of compliance with the feed ban by routine inspections of both renderers and feed mills. Third, Canada has traced and destroyed all remaining cattle imported from the UK. Fourth, Canada has traced and destroyed the majority of the cattle that comprised the birth cohorts of the two initial Canadian BSE cases, as it has subsequently done with the birth cohorts of the two most recent cases. Fifth, Canada has conducted surveillance for BSE since 1992 and has conducted targeted surveillance at levels that have met or exceeded OIE guidelines since 1995.

As we explained in our final rule, even if BSE-infected cattle do remain in Canada, they are likely to be older animals that were exposed before Canada's feed ban in 1997. Because this rule requires that imported animals be less than 30 months old, such animals could not legally enter the United States under this rule. Further, even if an infected animal did enter the United States, the science, the research, and the experience of animal and public health authorities, supported by the Harvard-Tuskegee Study indicates it would be very unlikely to lead to the introduction of BSE into domestic cattle or to human exposure to the BSE agent.

Several commenters on the EA questioned Canada's feed ban due to press reports published in December 2004 that revealed that animal protein of undetermined origin had been found by CFIA in ruminant feed. As part of its ongoing compliance and enforcement program, the CFIA conducted a small feed sampling and testing program to evaluate the usefulness of direct microscopy. CFIA concluded that microscopy was not capable of distinguishing between animal tissues that pose no animal health risk and those that are prohibited under Canada's

feed ban regulations. In following up on the microscopy results, the CFIA concluded the great majority of samples did not contain prohibited material. Of the 110 samples tested, 65 samples were of Canadian origin, 44 samples were from the United States, and one was from France. Of the 65 samples of Canadian origin, the CFIA was unable to rule out the possibility that some incidental level of prohibited material may have been present in 11 samples. Of the 45 imported samples, animal material was detected in 18. With respect to the Canadian origin samples, the CFIA has taken action to ensure that the establishments involved have improved their recordkeeping, flushing, and/or sequencing procedures. (*http://www.inspection.gc.ca/english/anima/feebet/rumin/microe.shtml.*) Based on our extensive experience and interaction with CFIA program officials over many years, the thorough Canadian report on the microscopy sampling and testing program, as well as the results of the APHIS feed team inquiry, APHIS has concluded that the Canadian feed ban is effective and will accomplish its objective of reducing and eliminating any BSE infectivity that may remain in Canada.

As noted above, several commenters expressed concern that the MRR rule could result in the introduction of BSE into the domestic herd and that vCJD could occur as a result of such introduction or through the import of meat products from Canada. With regard to this concern, there is a solid scientific consensus regarding our knowledge of the cattle tissues that contain BSE infectivity and our knowledge of the modes of transmission of that infectivity. While it is likely that ongoing research will increase our knowledge of the disease agent, APHIS, along with FSIS and FDA, are confident that the measures in place will protect animal and human health. In addition, it seems clear that there is a significant species barrier that protects humans from illness due to exposure to the BSE agent. European scientists working on the outbreak in the UK and subsequent BSE research have suggested that the amount of infective tissue required to infect humans may be 10,000 times greater than the amount needed to infect cattle. During the epidemic in the UK, it was estimated that there were approximately 1 million infected animals and yet, to date, there have been only approximately 153 vCJD cases worldwide, 95 percent of which have occurred in the UK. Current research does not suggest the need for further food safety mitigations and does not alter the conclusion that the appropriate tissues that can carry levels of infectivity sufficient to cause human or animal illness are, in fact, being removed from the animal and human food supply under U.S. and Canadian regulations.

One commenter suggested the need for further assessment of the persistence of the BSE agent in soil, water and air. To date, there is no evidence of environmental transmission of the BSE agent. While such transmission could be theoretically possible, epidemiological reviews do not indicate that such transmissions, even if they occurred, would be a significant issue. In the UK, which has experienced the largest and most significant outbreak, early epidemiological investigations pinpointed feed as the route of transmission. In response to these findings, the UK authorities instituted feed ban regulations that have been strengthened over the years. The feed restrictions have clearly had an effect in preventing transmission of disease, with the number of cases identified annually continuing to decrease from a peak in 1992–1993. Investigations have been done on animals born after the reinforced ban went into effect. These have included evaluating all possible routes of transmission, and they continue to conclude that environmental contamination is an unlikely risk factor. Therefore, based on the best available science, the ability of the BSE agent to persist in soil, water and air is not a significant issue.

While there is evidence that scrapie disease in sheep and chronic wasting disease (CWD) in cervids can be transmitted by environmental contamination, there is no basis for extrapolating these data to BSE in cattle. Research has demonstrated that the distribution of scrapie infectivity in sheep is different than the BSE agent in cattle. For example, infectivity has been found in the placenta of sheep infected with scrapie. This contributes to the lateral transmission (animal-to-animal) of scrapie in sheep, and if placental tissue remains in the environment, it can contribute to environmental contamination. Conversely, in cattle infected with BSE, no infectivity has been demonstrated in placenta and there is no evidence of lateral transmission of the disease. Similarly, animal-to-animal contact appears to contribute to the spread of CWD in cervids, and environmental contamination also appears to be a factor, although the specific means of transmission is unknown. However, these findings cannot be extrapolated to cattle with BSE, as there is no evidence of lateral transmission of BSE or of transmission by environmental contamination.

C. The Degree to Which the Action May Establish a Precedent for Future Action With Significant Effects or Represent a Decision in Principle About a Future Consideration

This criterion requires consideration of whether an action may establish an authoritative rule, pattern, or practice for similar cases that may follow and whether the precedent thereby established could have significant effects on the quality of the human environment.

The MRR rule establishes standards for recognizing regions as presenting a minimal risk of introducing BSE into the United States and provides for the importation of certain ruminants, ruminant products and byproducts from such regions. The minimal-risk region standards and import conditions established by APHIS are designed to prevent the introduction of BSE into the United States. These standards and conditions are buttressed by a series of interlocking, overlapping risk mitigations in place in the United States. The addition of this minimal-risk category to the agency's BSE rules will permit regions that believe they meet the standards to request recognition as a BSE minimal-risk region. We would expect and require that any such request will, in the first instance, comply with § 92.2 of the APHIS regulations, which contains the general procedures for requesting the recognition of regions. (9 CFR 92.2.) The MRR rule, however, designates Canada as the only minimal-risk region for BSE. Before another country or region would be recognized as a BSE minimal-risk region, APHIS would conduct an assessment of all risks involved. If the risk assessment indicated that the region meets the standards and appropriate requirements, APHIS would publish a proposal in the **Federal Register**. At that point, the public would have an opportunity to participate fully and all pertinent issues, questions, and concerns would be addressed in the rulemaking process. Needless to say, any unusual or unique facts or circumstances related to a particular region's request would be carefully evaluated by APHIS as well. For example, the animals or animal products allowed to be imported and the required risk mitigation measures could and would be tailored to each specific region considered. Accordingly, the MRR rule does not establish a precedent for future actions with significant effects or represent a decision in principle about future

approval of additional minimal-risk regions.

D. Whether the Action Is Related to Other Actions With Individually Insignificant but Cumulatively Significant Impacts

The term cumulative impact is defined as an impact on the environment that results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period of time.

The potential for harm to the quality of the human environment lies in the introduction of the BSE agent into the United States and subsequently finding its way into the animal and human food supply where it could be ingested and result in infection. For this chain of events to occur, the multiple animal and human health mitigation measures in place in Canada and the United States, as well as the additional mitigations prescribed by the MRR rule, would have to substantially fail. There is no basis to conclude that such a significant breakdown in the system of interlocking and overlapping measures could ever occur. Similarly, if the agency were to recognize any other regions as minimal-risk regions, there is no reason to believe that the mitigation measures and other requirements imposed in such a rulemaking would be any more likely to be breached and result in harm to animal or human health. It must be remembered that our MRR rule is designed to preclude the introduction of BSE into the United States and APHIS has concluded that the rule will achieve that result. Accordingly, there is no basis to believe that this action, or future actions that the agency may take, could result in cumulatively significant environmental impacts.

Additional Issues: Allegations of Environmental Impacts Raised in Litigation

Shortly after issuance of the final EA for the MRR rule, the Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America ("R–CALF"), filed a complaint challenging the rule in the United States District Court for the District of Montana. R–CALF alleged that the final EA was inadequate because, among other things, it failed to assess the environmental effects of transporting what we estimated would be as many as 2 million head of cattle from farms and feedlots in Canada to feedlots and slaughterhouses in the United States, as well as the environmental impacts of feeding and holding these additional feeder cattle until slaughter. Although the plaintiff filed several comments on the rule throughout this rulemaking proceeding, it did not include these concerns in these comments, nor did it file any comment on the final EA published on January 4, 2005. In addition, no other commenter on the EAs raised these potential environmental impact issues. Even though the alleged potential effects pose no significant environmental impact, and were not raised by R–CALF or any other commenter on the EA, we have addressed them below.

The two issues raised by R-CALF did not, and do not now, pose potentially significant impacts. Accordingly, they were not discussed in the final EA. First, it is important to note that the impacts or effects alleged by R-CALF to be significant are not brought about or caused by the MRR final rule. Second, it is also important to understand the MRR rule within the context of the economic relationship that has existed between Canada and the United States for many years. Since the 1970's, the U.S. and Canadian cattle and beef industries operated largely as an integrated North American industry, with both live cattle and processed beef flowing freely between the two countries. For years prior to May 2003, millions of head of live cattle crossed the border in one direction or the other. The two countries have become each other's largest trading partners in agricultural products.

In May 2003, as a result of the finding of BSE in Canada, APHIS published an interim rule to add Canada to the list of countries in which BSE exists. APHIS took this action as a temporary measure while it assessed the facts and circumstances surrounding the BSE situation in Canada. After evaluating the epidemiological investigation of the May 2003 BSE positive cow and after reviewing the BSE risk mitigation measures in place in Canada and the United States, USDA announced in August 2003 that it would begin issuing permits, pursuant to its existing regulations, to allow the importation of certain low-risk meat products from Canada. These products included boneless beef from cattle under 30 months of age, veal, and bovine liver. As a result, within 3 months, a substantial amount of trade in beef and beef products was resumed with Canada. In November 2003, APHIS issued a proposed rule that would again allow the importation of certain live animals, including cattle under 30 months of age, as well as all beef products from cattle under 30 months of age, from Canada. Therefore, the MRR rule would allow the restoration of trade in ruminants and ruminant products under approved mitigations after a temporary suspension of such trade.

The final economic analysis for the MRR rule estimated that as many as 2 million head of cattle could be imported from Canada in 2005, assuming implementation of the MRR rule at the beginning of the year. This estimate was based on historical cattle import data from 2001 and 2002, an estimated backlog of cattle in Canada as a result of the temporary closure of the border to live cattle in 2003, and an estimate of the number of cattle under 30 months of age that would be available for importation into the United States because of an increase in the number of older cattle that would be slaughtered in Canada for the export of beef to the United States. We acknowledged that there was a good deal of uncertainty in projecting the number of cattle that would be imported from Canada and that changes in production, feeding, slaughter and trade patterns and circumstances could well affect the result. In recognition of these uncertainties, we also conducted the analysis using one-half of the assumed backlog and one-half of the assumed number of imported fed cattle displaced from slaughter in Canada.

Using the 2 million number, R–CALF estimated that the resumption of limited trade in live cattle would result in 35,000 truck round-trips between Canada and the United States. Assuming these would represent an actual increase in trips involving live cattle and meat, the truck traffic represented by this estimation is wholly insignificant. For 2003, the incoming truck crossings from Canada into the United States totaled 13.3 million crossings, which included 6.7 million truck crossings, 5.7 million loaded truck container crossings, and 0.9 million unloaded truck container crossings. (*See http://www.bts.gov/programs/international/border_crossing_entry_data/.*) For 2002, the total incoming truck crossings from Canada into the United States were 13.7 million crossings, which included 6.9 million truck crossings, 5.8 million loaded truck container crossings and 1.0 million unloaded truck container crossings. (*Id.*) For 2001, the total incoming truck crossings from Canada into the United States were 13.4 million crossings, which included 6.8 million truck crossings, 5.6 million loaded truck container crossings, and 1.0 million unloaded truck container crossings. (*Id.*)

There is little variation in the annual volume of truck traffic entering the United States from Canada over this 3-year period, and, in addition, an increase of 35,000 truck crossings would be well within the variation shown by the data. Even with an increase of 35,000 truck round-trips between Canada and the United States, the total increase would amount to approximately 1/4 of one percent increase in truck traffic, an amount that is *de minimus* by any measure. An examination of truck traffic through the 20 ports of entry through which importations of live ruminants and ruminant products from Canada are authorized under the MRR rule yields similar conclusions. The 2003 truck crossings at the 20 ports of entry were approximately 11.1 million. (*Id.*) Therefore, an increase of 35,000 truck crossings spread over just these 20 ports of entry would result in less than 1/3 of a one percent increase. It is also important to note that truck traffic between the United States and Canada is merely a subset of all vehicular traffic between the two countries. When considering the total volume of all vehicular traffic traveling across the border with Canada, the environmental impacts associated with an increase of 35,000 truck round-trips are even less significant. Accordingly, R–CALF's claim that increased truck traffic would result in environmental damage is without merit.

R–CALF also alleges that there will be significant environmental effects attendant to the importation of live animals for feeding and for slaughter. R–CALF asserts that these live cattle would be required to be moved to a limited number of feedlots and slaughter facilities in the United States. However, the final regulation contains no limitation on the number of feedlots or slaughter facilities. The MRR rule is merely restoring, for live cattle under 30 months, longstanding trade with Canada, trade that has persisted for years and was only temporarily halted in May 2003 due to the finding of BSE in Canada. There is no reason to believe that these cattle would be destined for a different set of feedlots or slaughter facilities than cattle imported from Canada prior to 2003.

Whatever the potential environmental effects that theoretically might be associated with the importation of live cattle for feeding or for slaughter, there would be a significant difference in the magnitude of such potential effects depending on whether the cattle were being transported directly to slaughter facilities or were destined for feedlots, where they may be fed for some period of time prior to moving to slaughter. The potential environmental effects, while inconsequential, would be significantly less for cattle moved immediately to slaughter facilities. Based on historical data for cattle imports from Canada, between 65 percent and 75 percent of imported cattle have gone directly to slaughter and the remainder (other than the very small number historically imported for breeding) have been transported to feedlots and then to slaughter facilities. Based on the projection in the final economic analysis of 2 million cattle imported, approximately 1.4 million would be moved immediately to slaughter and 600,000 feeder cattle would be moved to feedlots.

Subsequent to the estimates in the final economic analysis and publication of the MRR rule, on February 9, 2005, the Secretary announced that implementation of the part of the MRR rule that would allow for importation of beef from cattle 30 months of age or older would be delayed. Therefore, there was no longer a basis for assuming the displacement from slaughter in Canada of cattle under 30 months of age by cattle 30 months of age or older. The estimate of the number of cattle that would be imported from Canada was revised downward. We further modified the estimate downward to reflect an increase in Canadian slaughter capacity over the past year. Therefore, based on these factors, we estimated that as many as 1.4 million cattle could be imported from Canada in the first year after the effective date of the MRR rule. Of this number, we estimate that 900,000 fed cattle would be moved directly to slaughter facilities and that 500,000 feeder cattle would be sent to feedlots and then to slaughter, further reducing any potential impacts.

On January 6, 2005, the National Cattlemen's Beef Association (NCBA) sent a delegation of U.S. cattle producers to Canada on a fact-finding mission regarding BSE and the MRR rule. One task assigned to the NCBA delegation was to identify Canadian cattle that would qualify for export under the MRR rule and determine the impact on U.S. producers. The NCBA delegation report, dated February 2, 2005 (*http://www.beefusa.org/uDocs/acf985911.pdf*) stated, based on Can-Fax data gathered over a 20-month period of time, that there were approximately 900,000 head of cattle available for export. This consisted of approximately 600,000–700,000 head of fed cattle and approximately 200,000–300,000 feeder cattle. The NCBA report suggested that the import quantities assumed in APHIS' economic analysis were too high. The NCBA report suggests that the APHIS estimate did not fully account for the 22 percent increase in Canadian slaughter capacity between 2003 and 2004. The NCBA report concluded that the delegation agreed with Can-Fax and other private sector estimates and put the likely imports of feeder cattle in the range of 200,000–300,000 during calendar year 2005 and assumed that the MRR rule would be implemented on March 7, 2005.

Under either of APHIS' two estimates, any environmental effects would not be significant. The average annual number of fed cattle slaughtered for the years 2002 and 2003 in the United States was 29 million. Total cattle slaughter, which includes fed cattle, cows and bulls, averaged 35.6 million head annually for the same period. Thus, the estimated maximum imports of cattle for immediate slaughter would amount to approximately 4.8 percent of the total fed cattle slaughter and 3.9 percent of total cattle slaughter spread over a 12-month period. For the years 2003 and 2004, an average of 26.9 million cattle were marketed by U.S. feedlots annually. The estimated number of feeder cattle that may be imported from Canada in the first year (500,000–600,000 head) would represent between 1.8 and 2.2 percent of fed cattle marketed annually in the United States. Even assuming that Canadian feeder cattle actually imported after implementation of the MRR rule represented an actual increase in the number of cattle on feed in the United States, the potential effects would not be significant. The transitory nature of even this volume of imports from Canada is discussed in the final EA, where estimates that imports would decline over the years 2006–2009 are discussed and displayed.

Furthermore, any potential impacts on air and water quality associated with the importation of cattle from Canada are addressed under an array of existing statutes and regulations in the United States. These regulations include the National Pollutant Discharge Elimination System Permit regulations and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFO) under the Clean Water Act, as well as State environmental regulations for proper management of manure and wastewater from animal feedlot operations. In addition to state laws and regulations for air emissions, there are a variety of provisions under the Clear Air Act that could address air emissions relating to this activity. The U.S. Environmental Protection Agency has also established requirements for CAFOs under the

Clean Water Act and regarding nitrate contamination of underground sources of drinking water under the Safe Drinking Water Act. The United States' Clean Air Act and Canadian environmental protection laws have vehicle emissions requirements that are designed to prevent harmful air emissions from vehicles, including transport trucks. These activities have a very low potential to negatively affect human health and safety since each is subject to comprehensive environmental regulation in this country and in Canada. Compliance with these requirements by transporters, feedlot operators, and slaughterhouses assures that the quality of the human environment will be safeguarded in all respects. Our border ports are adequately staffed and capable of handling movement of cattle into this country, which will not concentrate at a single border port. Historically, Canadian cattle imported into the United States for slaughter have been shipped to numerous States throughout the United States. Because cattle are not required to be shipped to specific feedlots or slaughter facilities, it is expected that trucks will utilize all available border crossings and highway routes. There is no evidence or data to suggest that our roadways, feedlots, and slaughterhouses, as currently operated, cannot accommodate the resumption of Canadian cattle imports in a manner that fully protects all potentially impacted environmental quality values.

I have determined that the final BSE MRR rule will not have a significant effect on the human environment and accordingly I have decided that it is appropriate to issue a finding of no significant impact for the final MRR rule. Thus, having fully considered the two environmental assessments prepared for the MRR rule, as well as all of the comments submitted on them, along with the reports and analyses referenced in the EA and in the MRR rule, I conclude that the MRR rule will protect animal and human health and the environment. Accordingly, I find that adoption of the MRR final rule and the recognition of Canada as a BSE minimal-risk region will not significantly affect the quality of the human environment.

The finding of no significant impact was signed by Dr. W. Ron DeHaven, Administrator, Animal and Plant Health Inspection Service, on April 5, 2005.

Done in Washington, DC, this 5th day of April 2005.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

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